IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF
WEST VIRGINIA AT CHARLESTON

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IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:Master File No. :2:12-MD-0237 : :MDL No. 2327
THIS DOCUMENT RELATES TO THE CASES LISTED BELOW	:JOSEPH R. GOODWIN :U.S. DISTRICT JUDGE

Mullins, et al. V. Ethicon, Inc., et al.
2:12-cv-02952
Sprout, et al. V. Ethicon, Inc., et al.
2:12-cv-07924
Iquinto v. Ethicon, Inc., et al.
2:12-cv-09765
Daniel, et al. V. Ethicon, Inc., et al.
2:13-cv-02565
Dillon, et al. V. Ethicon, Inc., et al.
2:13-cv-02919
Webb, et al. V. Ethicon, Inc., et al.
2:13-cv-04517
Martinez v. Ethicon, Inc., et al.
2:13-cv-04730
McIntyre, et al. V. Ethicon, Inc., et al.
2:13-cv-07283
Oxley v. Ethicon, Inc., et al. 2:13-cv-10150
Atkins, et al. V. Ethicon, Inc., et al.
2:13-cv-11022
Garcia v. Ethicon, Inc., et al. 2:13-cv-14355
Lowe v. Ethicon, Inc., et al. 2:13-cv-14718
Dameron, et al. V. Ethicon, Inc., et al.
2:13-cv-14799

SEPTEMBER 17, 2015
JERRY G. BLAIVAS, M.D.

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CAPTION CONTINUED:

Vanbuskirk, et al. V. Ethicon, Inc., et al.
2:13-cv-16183
Mullens, et al. V. Ethicon, Inc., et al.
2:13-cv-16564
Shears, et al. V. Ethicon, Inc., et al.
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Javins, et al. V. Ethicon, Inc., et al.
2:13-cv-18479
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Stevens v. Ethicon, Inc., et al.
2:13-cv-29918
Harmon v. Ethicon, Inc., et al. 2:13-cv-31818
Snodgrass v. Ethicon, Inc., et al.
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Miller v. Ethicon, Inc., et al. 2:13-cv-32627
Matney, et al. V. Ethicon, Inc., et al.
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Jones, et al. V. Ethicon, Inc., et al.
2:14-cv-09517
Humbert v. Ethicon, Inc., et al.
2:14-cv-10640
Gillum, et al. V. Ethicon, Inc., et al.
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Tyler, et al. V. Ethicon, Inc., et al.
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Kelly, et al. V. Ethicon, Inc., et al.
2:14-cv-22079
Lundell v. Ethicon, Inc., et al.
2:14-cv-24911
Cheshire, et al. V. Ethicon, Inc., et al.
2:14-cv-24

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SEPTEMBER 17, 2015

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Oral deposition of JERRY G. BLAIVAS, M.D., taken pursuant to notice, was held at the law offices of Drinker Biddle and Reath, LLP, 1177 Avenue of the Americas, 41st Floor, New York, New York 10036, commencing at 9:56 a.m., on the above date, before Amanda Dee Maslynsky-Miller, a Certified Realtime Reporter and Notary Public in and for the State of New York.

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I N D E X

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Testimony of: JERRY G. BLAIVAS, M.D.

- - -

E X H I B I T S

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DEPOSITION SUPPORT INDEX

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Stipulations

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None					

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(It is hereby stipulated and agreed by and among counsel that sealing, filing and certification are waived; and that all objections, except as to the form of the question, will be reserved until the time of trial.)

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JERRY G. BLAIVAS, M.D., after having been duly sworn, was examined and testified as follows:

- - -

EXAMINATION

- - -

BY MR. SNELL:

Q. Good morning, Doctor.

A. Oh, hi.

Q. Could you please state your full name for the record, please?

A. Jerry G. Blaivas.

Q. And you are a neurological surgeon here practicing in New York City?

A. I am.

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Q. You and I have met before. I'll reintroduce myself on the record.
My name is Burt Snell. You're aware that I represent Ethicon and Johnson & Johnson in the mesh litigation?
A. Correct.
Q. And you understand we're here today to take your -- strike that.
You understand we're here today to take your deposition in a case of -- it has multiple plaintiffs, the first one is named Mullins, with regard to the TVT retropubic device?
A. I do.
Q. And you know that the TVT retropubic device is a device manufactured by Ethicon, correct?
A. Correct.
Q. In front of you is deposition Exhibit Number 1, which is your notice of deposition.
- - -
(Whereupon, Exhibit Blaivas-1, Notice of Deposition of

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J. Blaivas, was marked for identification.)
- - -
BY MR. SNELL:
Q. Have you seen that before?
A. I have.
Q. On the third page -- sorry.
Schedule A identifies different documents and materials that we requested that you bring to the deposition.
Did you bring any materials here today, sir?
A. I did not.
Q. I understand that you have an updated C.V.?
A. I believe so. It's in process.
MS. FITZPATRICK: We will be -- I'll get you that this morning, but certainly before the lunch break.
MR. SNELL: We'll just make a note, and we'll mark his C.V. as

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Exhibit Number 2, when it arrives.
MS. FITZPATRICK: And also just for the record, we have filed objections to the notice and, particularly, to the document request in Schedule A.
BY MR. SNELL:
Q. Why did you not bring any materials with you to the deposition today, Doctor?
A. Well, the first two things I didn't have, we didn't complete yet. And I was advised not to bring the remainder.
Q. How many hours have you spent on the Mullins case?
A. By "the Mullins case," you mean today's case, not as an individual?
Q. Correct. Today's case for which you're giving a deposition.
A. In total, approximately 20 hours.
Q. And what is your rate?
A. $750 an hour.
Q. Is that for review and

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preparation of a report, as well as sitting for a deposition?
A. No. There's a separate fee for sitting for the deposition.
Q. Can you just tell me your fees quickly?
A. $15,000 for a lawsuit, for an entire day. And $7,500 for half a day.
Q. And the $15,000 for a day, that's for a full day's testimony?
A. For the full day, yes.
Q. Where do you currently work?
A. My office -- well, I'm in practice of urology. And I have an office on 77th Street in Manhattan, and I work sometimes there, sometimes the hospital, sometimes from home; different places.
Q. Are you affiliated with, still, Weill Cornell?
A. I am.
Q. Are you on staff at Weill Cornell or are you private in your

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practice?
A. I'm private. I'm a clinical professor of urology there.
Q. Do you still perform your stress urinary incontinence surgeries at Weill Cornell?
A. I do.
Q. Do you perform any of your stress urinary incontinence surgeries in your office?
A. Well, to the extent that periurethral injections are considered a stress incontinence operation, I would say yes.
Q. Do you consider periurethral injections a stress urinary incontinence operation?
A. Technically, it is, yes.
Q. Setting periurethral injections aside, what are the stress urinary incontinence surgeries that you currently perform today?
A. Essentially, autologous slings.

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Q. When you say "autologous slings," is that the same thing as autologous fascial slings?
A. Yes.
Q. Are there any other descriptors in the literature, or in your profession, that describes autologous slings besides fascial, autologous fascial slings?
A. Yeah, there's a number. I would say the most complete one would be autologous rectus fascial sling or autologous fascial lattice sling; or some people just use the word pubovaginal sling.
I think those are the ones that come to mind. Fascial sling.
Q. So today if we are discussing autologous fascial pubovaginal slings, we'll be discussing slings that utilize the woman's own tissues; is that correct?
A. Correct.
Q. And those are different than

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the midurethral slings like my client makes, like the TVT, which are synthetic slings, correct?
A. Yes. But, technically, a synthetic sling could be used in the mid urethra or proximate urethra and so could an autologous sling. So an autologous sling could be used as a midurethral sling.
Q. The way you put in the autologous slings, what location of the urethra do you put them at?
A. I put them at the bladder neck.
Q. Why do you put the autologous sling at the bladder neck?
A. Well, one, I think it makes physiologic sense to put it there.
And, two, it's a tried and true method and, certainly, you know, historically the gold standard using that technique.
Q. To your knowledge, in the urologic surgical community, what rate of

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urologists use autologous slings but place it at the mid urethra?
MS. FITZPATRICK: Objection to form.
THE WITNESS: Very few, but some do.
BY MR. SNELL:
Q. Do you know who -- which those individuals would be?
A. I don't remember, but I've seen papers that talk about it.
Q. So it would be correct that you do not offer the Burch colposuspension to patients?
MS. FITZPATRICK: Objection.
THE WITNESS: There might be a rare circumstance where -- where I might consider using one. But I don't -- it's not my first line.
And, in fact, I can't remember the last time I did one.
BY MR. SNELL:
Q. Were you trained on the Burch colposuspension at some time in

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your medical training or professional career?
A. Yes, I was.
Q. By who?
A. More precisely, I was trained on the Marshall-Marchetti, which is not quite a variant, but they're very similar. And in the course of doing that, there was a time when I did, you know, a number of Burches as well.
Q. What is the last time you did a Marshall-Marchetti-Krantz colposuspension procedure?
A. I'm going to guess in the early '80s, 1980s.
Q. And who was it who introduced you to the Marshall-Marchetti-Krantz procedure?
A. A fellow by at that name of Bob Spellman. He was a urologist who actually trained with Victor Marshall, who was the developer of the procedure, and -- during my residency training.
Q. Is the

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Marshall-Marchetti-Krantz procedure done commonly today?
A. No.
Q. What is the difference in risk between a Marshall-Marchetti-Krantz colposuspension and a Burch colposuspension?
A. In my judgment, I think the Burch has a higher likelihood of injuring the ureter. And aside from that, I think they're fairly comparable.
There are technical things, like some people that, when they did a Burch would use a nonabsorbable suture, which really isn't the procedure itself but the sutures they chose to use. So that, I think, posed an additional risk.
Q. I have read that the -- can I call it the MMK to make it easier on her?
A. Sure.
Q. Is it correct, Doctor, that the MMK is associated with a risk of osteomyelitis?

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A. Osteomyelitis and osteitis pubis, yeah. I think it's a small risk, but yes.
Q. And that can be a significant complication in women?
A. A rare one, yes.
Q. Is the Burch associated with a potential risk of osteomyelitis?
A. I don't think so, but I couldn't be sure.
Q. In your report, you discuss how you have taken GYNEMESH® and fashioned it as a strip of mesh to treat stress incontinence in certain second-line or third-line cases, I take it; is that correct?
A. My recollection is that it was soft PROLENE® mesh. But I could be -- it's possible that I've used GYNEMESH® in the past. I don't really have an independent recollection of that.
Q. Your report says that you use a strip of GYNEMESH® in a Stamey needle to put that mesh in?

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A. The problem is, at the time I did that, there was -- neither myself, nor hardly any other urologist, or anybody who was doing these surgeries, had any idea that there was much of a difference between the meshes.
So we would -- speaking for myself, at least, and I'm sure my peers, we would have used -- might have used the commercial names for different meshes synonymously; like, I wouldn't have, at that time, made a distinction, in my mind, between GYNEMESH® and soft PROLENE® mesh. It was literally we would have used what was available at that hospital at that time.
Q. And do you still offer mesh -- strike that.
Do you still offer -- strike that.
The GYNEMESH® sling that you fashioned, hand-fashioned, was that the Ethicon mesh?
A. I believe so.

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Q. And you understand the Ethicon mesh is made of PROLENE® polypropylene?
A. I do.
Q. And do you still offer synthetic mesh slings to patients as a second or third or fourth-line option?
A. I discuss the risks and benefits, and I do go through the differences -- well, I already said that.
I discuss the risks and benefits. And in a rare patient, it's possible that I might think that a mesh is suitable for them.
And I'm talking now just about, just about slings, not about vaginal -- not about prolapse mesh.
And, overall, my opinion is that the risks of synthetics far outweigh the benefits. There are highly selected patients for whom that risk/benefit ratio might be reversed.
Q. You mentioned prolapse transvaginal mesh or prolapse mesh.

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You do not currently do pelvic organ prolapse surgery; is that correct?
A. No, I do.
Q. Oh, you do.
Do you use any type of mesh in your prolapse surgeries?
A. I do not.
Q. Do you do any abdominal sacrocolpopexies?
A. Rarely, but yes. But I do that with fascia, I don't do it with synthetic mesh.
Q. All right. So I want to get back and just really focus on stress incontinence.
And when was the last time you used the PROLENE® polypropylene mesh for a sling in a patient?
A. Some time in the early '90s.
Q. And today when you counsel a patient about the potential risk of the PROLENE® polypropylene mesh, what risks do you identify to her?

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A. Well, what I do is I tell the patients that they are -- I divide them into those risks that would make you -- are common enough and/or lifestyle altering enough that would make you consider not having the operation, and those risks that are so rare and inconsequential that it doesn't usually come into the decision-making process.
And when I tell them what the risks are, it's that I think there's about somewhere between a minimum of a 15 to 20 percent -- say 15 percent negative outcome from having a synthetic mesh sling that would make you, in retrospect, have wanted to not have had the surgery. If you knew one of these complications might have happened to you, you would have said, this is a quality-of-life issue and I don't want to do that.
And those risks are urethral obstruction requiring surgery; erosion, whether it requires surgery or not; pain; recurrent stress incontinence; and the

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development of de novo overactive bladders, frequency and urgency in urination. I think I left out one.
I may have left out one, but I can't -- I don't remember right now.
Oh, dyspareunia, that's what I left out, which, of course, is a form of pain.
Q. And what are the selected patients for whom you would consider offering a synthetic polypropylene sling to?
A. I would say a patient with -- that has no likelihood of engaging in or wanting to engage in sex, who is obese or morbidly obese, and a poor surgical risk.
Q. And the patients -- strike that.
In the selected patients for whom you would offer a polypropylene sling, do you have a preference as to the material?
A. No. I would use, I would

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really investigate it at the time and see what I think the best product is. And, again, I haven't done one in probably eight or nine years, at least, and I would try to pick the one that I thought had the least chance of having a complication.

And I would use the shortest sling that I thought was reasonable. So I would use a -- you know, ordinarily with a fascial sling, it goes all the way into the retropubic space, practically to the fascia on either side, which is roughly 18 centimeters long. For a synthetic sling, I would use one that's maybe six or -- six or eight centimeters long so that it didn't -- either didn't go into the retropubic space or it didn't go in very far.

And the reason is then it would be quite easy -- it would be pretty easy to take it out if I needed to.

Q. Have you ever used any synthetic mini-slings made of

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polypropylene?

A. I've cut them myself to make the -- I have not used any sling kits, but I have done just what I said; I've used what might be considered almost a mini sling, just hand fashioned.

Q. And were those hand-fashioned slings polypropylene slings?

A. Yes.

Q. Were they most likely Ethicon branded polypropylene slings?

A. Yes.

MS. FITZPATRICK: Objection.

BY MR. SNELL:

Q. Did you have any negative outcomes with those hand-fashioned Ethicon branded slings?

A. I did. I had a couple that were -- that contracted and became -- it became obstructive, and I had to excise them.

Q. How many of the Ethicon slings that you put in became contracted?

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A. I remember two. But I didn't put very many in. So the denominator wasn't very high.

Q. Of those two slings that you recall that were Ethicon branded that became contracted, how many of them did you surgically go in to fix?

A. You mean after we cut them, did we go back and do another sling?

Q. I guess my question was, for the two Ethicon slings that you put in that you remember contracted, did you go in and release those slings because of the obstruction?

A. Yes. Yes.

Q. And describe how you would have released that sling.

A. You mean the surgical technique?

Q. Yes.

A. I don't do it this way anymore, but I do remember what I did then is I made an incision over the sling. I dissected between the sling and

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the urethra and created a plane. And then simply incised it in the middle by dissecting it off the urethra and just -- that's all I did. And it just sprung open.

Q. Okay. Do you know if there was -- strike that.

At what point after implantation did this contraction occur in these two patients?

A. Within the first year. I can't remember exactly. And it was past the perioperative period, so I would say somewhere between three and six -- three and twelve months.

Q. Do you recall whether these two women remained continent after you released the polypropylene Ethicon branded sling?

A. One -- neither one remained continent, but neither -- neither one remained continent, I remember that.

Q. Did either one of them require the placement of some other

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stress urinary incontinence surgery after you removed the sling?
A. Well, neither one elected to have another operation. You never require it, you elect it.
Q. You have not published in the literature on these two patients, have you?
A. No.
Q. Have you calculated any statistics on these two patients as compared to the total number of patients for whom you put in an Ethicon branded polypropylene sling?
A. Yeah, it was only about ten patients so, I mean, it would be probably -- in that case, maybe 20 percent.
Q. Explain to me how you would go about cutting the Ethicon branded mesh in order to make it into a polypropylene sling for stress urinary incontinence.
A. Well, I wouldn't do that now -- I wouldn't that the way I did it.

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But I just took a strip about 10 centimeters -- excuse me, 2 centimeters wide and then just approximated how long I wanted it and just cut a rectangle.
Q. How wide of a strip of the Ethicon branded poly mesh --
A. 2 centimeters, I said.
Q. Would you just cut it with surgical scissors?
A. Yes.
Q. You said you wouldn't do it that way now.
What do you mean by that?
A. I mean, I try -- actually, I said that. But I don't know what I meant by that.
I mean, I know the potential problems of cutting it, the potential negative consequences of fraying and things like that. So -- I mean, if I was going to use a synthetic sling, I suppose there's no other way of doing it, that I know of, other than cutting it.
So I guess I would do it

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that way again, if I was going to use it.
Q. When you hand cut the Ethicon branded slings, would you do that in the operating suite?
A. Yes.
Q. Do you see any particles of the mesh fall off when you hand cut the mesh?
A. I wouldn't -- I don't think I would have noticed.
Q. Did you see any particles of the mesh get into the woman's body during your surgical implantation?
A. Again, I wouldn't have noticed. I wouldn't have thought -- at the time, I didn't know some of the things that I know now, so it would have been a non-event for me then.
Q. But do you recall any particles being in the woman's vagina when you were putting in the mesh?
A. I don't recall.
Q. Why would you cut the mesh at a widths of 2 centimeters?

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A. Because I would want a broad enough base so that it wouldn't cut through. But that's about -- that's the same width that I make the autologous slings, so that's where I got the guideline from.
Q. Where would -- strike that.
Where at the urethra would you place the synthetic Ethicon branded sling?
A. This -- for the synthetic, I would place it at the mid urethra.
Q. Why is that?
A. Because that's what the data showed -- I mean, oh -- that's what the data showed -- excuse me.
That's the way the technique was described, and I didn't see any reason to modify it.
I'm sorry, were you asking me about -- you were asking me about then? I haven't done any in, like I say, a very long time.
Were you asking me how I did

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it then or -- was that your question?
Q. Yes. When you would place the Ethicon branded, you know, PROLENE® polypropylene sling for stress urinary incontinence, where at the mid urethra would you place it?
MS. FITZPATRICK: Objection.
THE WITNESS: As I said, I would place it in the mid urethra.
BY MR. SNELL:
Q. What data did you rely upon for the mid urethral placement of the Ethicon branded sling at the mid urethra?
MS. FITZPATRICK: Objection. Are you talking about the mesh or are you talking about a particular sling?
MR. SNELL: I'm talking about the slings he's testified he placed.
MS. FITZPATRICK: I just want to make sure we're clear here.
THE WITNESS: I haven't

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thought about this in a very long time, and it occurred to me that I misspoke just now.
In the few that I did, I did not place them at the mid urethra, I placed them at the bladder neck.
BY MR. SNELL:
Q. So in the few PROLENE® polypropylene slings that you placed at the bladder neck, why would you have chose that location?
MS. FITZPATRICK: Objection to form. I just want to make sure we're on the same page.
There's the slings that Ethicon makes, the TVT --
MR. SNELL: I know. You're making a speaking objection. What's your point?
MS. FITZPATRICK: I don't understand what your question is.
Are you talking about those or are you talking about where he has testified that he has hand cut

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some of the PROLENE® mesh before to place it? I'm not sure what you're talking about.
BY MR. SNELL:
Q. Have you ever placed a TVT?
A. No.
Q. Every Ethicon branded PROLENE® polypropylene sling you placed were slings that you hand cut, correct?
A. Correct.
Q. And you hand cut them at a 2 centimeter wide strip, correct?
A. Correct.
Q. And those are the slings -- synthetic slings, that you've done, correct?
A. That's correct.
Q. Okay. And you testified that you would place those -- strike that.
You changed your testimony, and you testified that you placed those at the bladder neck, correct?
MS. FITZPATRICK: Objection.

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THE WITNESS: Correct.
BY MR. SNELL:
Q. Why would you place them at the bladder neck?
A. Because I believe there's a learning curve for everything that you do. And even that little change from the mid urethra to the bladder neck, I didn't think it was necessary to subject the patient to a new learning curve for that part of the operation.
Because the autologous slings had been so successful, that I thought it best to -- to mimic exactly that same operation but using the synthetic sling because of other concerns.
Q. When you made the decision to place the PROLENE® polypropylene slings at the bladder neck, were you relying on any data in the medical literature for that determination?
A. Yeah, I was relying on my own published experience, published

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experience of others with the results of doing slings at the bladder neck.
Q. Did any of that literature concern the placement of synthetic mesh slings at the bladder neck?
A. It did not. But the literature, at the time -- excuse me.
The IFU and everything about PROLENE® mesh from Ethicon stated, over and over again, that it was inert, stayed the same, essentially did not change once it was in the body. So I had no reason to believe that it would behave, at least at the time, any differently than autologous mesh.
Q. When you hand cut the PROLENE® polypropylene mesh slings, did you look at the IFU before using those slings?
A. No, I didn't.
Q. Did you only use a Stamey needle in carrying out the placement of the PROLENE® polypropylene slings that you used for stress urinary incontinence?

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A. Yes.
Q. How did you tension -- strike that.
Did you tension the PROLENE® polypropylene slings that you placed for stress urinary incontinence?
A. I made a special effort to make it very, very loose.
Q. How did you do that?
A. I passed the sling and then I would pull up on it, pull up on both ends of the suture to confirm that it was in the position that I wanted to. Then I put -- then I put an instrument, a right-angle clamp, or something, and pulled it down so that there is plenty of space -- not that there was space, but so that it was loose.
And then I tied the sutures together above, with visual confirmation that there was no contact at all between the -- between the sling and the urethra.
And, generally, I would be able to get a finger -- well, my goal was

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to be able to get about a fingerbreadth between the sling and the urethra, which is actually much looser than what is described for the synthetic slings nowadays.
Q. What type of sutures would you use to tie the --
A. PROLENE®.
Q. And what -- when you fashion your autologous slings, did you ever use PROLENE® sutures?
A. In the early years, I did. I'd say until about probably some time around 2000, I just changed to a delayed nonabsorbable.
Q. Why did you make the change from the PROLENE® to the delayed absorbable sutures around 2000 for your autologous slings?
A. Because I just didn't -- I didn't see the need for a permanent suture.
Q. When you were -- strike that.

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Who originally trained you on the performance of an autologous sling for stress incontinence?
A. Well, nobody actually trained me, except at the extent, possibly, of McGuire. I mean, I went and visited McGuire, I think, in about 1980 or 1981, when he was still at Yale, and I watched him do a couple of slings. But that was the extent. They weren't being done for practical purposes before he reintroduced it and I picked it up.
Q. I guess my question is, then, why did you use permanent PROLENE® sutures for your autologous fascial slings before 2000?
A. I suppose out of ignorance, but a community-wide ignorance, of the necessary of using permanent sutures. We just thought that -- we didn't think about it very much, but the supposition was that you needed a permanent suture to make -- maintain the integrity of the strength of the sling.

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And then at some point, I just realized that that just wasn't true. And then you do have -- the problem is, occasionally, a person would get a stitch abscess or, in a skinny person, the PROLENE® can stick into the wound.

So just minor reasons, I mean, I -- but that answers your question.

Q. In the occasions where you did an MMK or a Burch, what type of suture would you use in those procedures?

A. It's been a long time, but I never used a permanent suture, so it would have been -- it probably would have been like a chromic catgut.

Q. Did you have any complications in your patients for whom you put the PROLENE® sutures in for your autologous slings for which you attributed that complication to the PROLENE® suture?

A. Aside from a rare -- maybe a rare stitch abscess that was a minor

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problem, the answer would be no.

Q. How many autologous fascial slings did you place using PROLENE® sutures?

A. I'm going to guess -- I mean, estimate maybe 1,500.

Q. And what year was it that you actually began doing the autologous fascial sling?

A. 1981 or 1982.

Q. Is it correct that you found the PROLENE® sutures that you used in your autologous fascial slings to be biocompatible in your patients?

A. Yes.

I'm sorry. I think I know what you mean, but what exactly did you mean by "biocompatible"?

Q. How about this: How do you define "biocompatible"?

A. I think in two ways -- one way -- well, I don't know. I haven't looked in the dictionary.

But in this kind of

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conversation, there's a biocompatibility that when you put it in the body, does the body accept it in a clinical sense and do no harm in a clinical sense. And for individual PROLENE® sutures like that, I would say the answer is yes, it's biocompatible.

But in a histopathologic sense, does the -- does the single strand of PROLENE® mesh incite an inflammatory reaction and serve as a foreign body to which the immune mechanisms of the body would try to reject, I would say, to a certain extent, that is true.

Q. So with regard to the clinical outcomes with your use of PROLENE® sutures in roughly 1,500 patients for your autologous slings, you found that material to be biocompatible, correct?

A. Clinically, yes.

Q. When you say "clinically," what do you mean by that?

A. By comparison, clinically,

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the vaginal and sling mesh is not clinically compatible because it causes an inflammatory reaction, probably -- well, because it causes an inflammatory and has clinical consequences.

MR. SNELL: Move to strike as nonresponsive.

BY MR. SNELL:

Q. What do you mean by "clinically biocompatible" when you were discussing the PROLENE® suture?

MS. FITZPATRICK: Asked and answered.

THE WITNESS: I already answered that.

BY MR. SNELL:

Q. No, you answered something about mesh. I was asking about the suture.

A. If you want to read it back, two questions ago, you asked me --

MS. FITZPATRICK: Asked and answered.

Go ahead.

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MR. SNELL: Can you read it back?
(Whereupon, the court reporter read the following part of the record:
"Question: When you say 'clinically,' what do you mean by that?
"Answer: By comparison, clinically, the vaginal and sling mesh is not clinically compatible because it causes an inflammatory reaction, probably -- well, because it causes an inflammatory and has clinical consequences.")
MR. SNELL: Note my objection when you said "by comparison." That was the basis of my objection.
THE WITNESS: The same question -- you started this series two questions ago, you asked me, how do you define clinical, and I said two ways.

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BY MR. SNELL:
Q. I know when I asked you to define biocompatible, you said there's two types, clinically and histopathologically.
And what I was getting to was, okay, I want to ask you, what do you mean by the "clinically" and what do you mean by "histopathologically"?
A. I did answer that question. I'm positive.
- - -
(Whereupon, a discussion off the record was held.)
- - -
BY MR. SNELL:
Q. So, Doctor, we were off the record and we read your testimony when I asked you what is a biocompatible, and you stand by the answer you gave?
A. I do.
Q. Okay. Is it correct, Doctor, that there can be inflammation and a foreign body reaction seen

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histopathologically but for which it does not manifest in clinically significant complications in a woman?
A. Yes, there can be.
Actually, I'm going to qualify that. Yes, there can be over the period of time that we've observed patients.
So it -- for example, a person may not have any consequences for -- there may be no consequences of this clinical inflammation for a decade or more, and then there may be clinical consequences from the same inflammation getting worse.
Q. I'm correct, you're not a pathologist?
A. That's correct.
Q. What is the correlation -- strike that.
Have you seen any -- strike that.
What is the correlation, if any, between histopathologic findings of

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inflammation and the rate at which those women have clinical symptoms from the inflammation?
A. It's impossible to answer that question because there's no denominator. So I can't tell you the incidence.
But I can tell you that when we remove mesh from patients, for whatever reason, and subject it to pathologic examination, in virtually 100 percent, there's chronic inflammation, and in many instances, acute inflammation.
Q. Are you relying -- strike that.
What's your methodology for that statement, that there's 100 percent --
A. I said near 100 percent.
MS. FITZPATRICK: Objection.
THE WITNESS: A number of papers that we've cited in this -- in my report, in our mesh review

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article, and in personal experience, going over almost 100 slides from 100 patients, pathologic slides, with Dr. Iakovlev.

BY MR. SNELL:

Q. Dr. Iakovlev is a pathologist?

A. A pathologist, yes.

Q. Does -- Dr. Iakovlev, did he review the slides that are in your article?

A. Yes, he wrote that section.

Q. Did you rely upon Dr. Iakovlev's knowledge and experience as a pathologist in allowing what he wrote to go into that article?

MS. FITZPATRICK: Objection.

THE WITNESS: In part. But I also vetted it with some pathologists that I discussed it with independently and had them read the section.

And I actually tried to

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get -- well, yeah, I'll just leave it at that. I vetted it with other pathologists.

BY MR. SNELL:

Q. What other pathologists did you vet Dr. Iakovlev's section on?

A. I'm not going to answer that.

Q. Why not? I mean --

MS. FITZPATRICK: Objection.

THE WITNESS: Because it was not in an official capacity, and I prefer not to mention their names.

BY MR. SNELL:

Q. Did you give those other pathologists the slides so they could look at the slides?

MS. FITZPATRICK: Objection.

THE WITNESS: No. I looked at the -- we looked at the photomicrographs that he took -- that he provided me with, and we talked about the methodology and things like that.

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So I got kind of an internal review of that.

And I'd like to remind you that the article itself was peer reviewed by a very stringent journal and accepted for publication.

And Dr. Iakovlev's other article -- other article dealing with this has been published in peer-reviewed publications.

BY MR. SNELL:

Q. Do you know if any of the reviewers in the peer-review process looked at the actual slides of these patients?

A. I don't believe they were provided the slides, nor did they ask. I think that would be very unusual -- I've not ever seen anybody ask for the slides.

And, actually, I was an editor of a journal, and no one -- I just don't think it's done.

Q. Have you ever been an editor

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of a pathology journal?

A. No. But the journal I edited did have pathology slides in it from time to time -- pathology papers in it from time to time.

Q. Why did you decide to review Dr. Iakovlev's analyses and review of the pathology with other pathologists?

A. Because I'm the senior editor of this paper, and I wanted to do my own, if you will, peer review to satisfy myself that the science was good.

Q. But you will not identify those pathologists?

A. No.

Q. Did you make any recordings of your conversations with these pathologists?

A. No.

Q. Did you make any notes with regard to your conversations with these pathologists?

A. No. This was more in the nature of explaining things to me. And I

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actually sat down with them and, you know, made sure that we were using appropriate stains and techniques and things like that.

I wanted to be sure that the methodology he was using was acceptable methodology and that the examples of pathology that he was showing were, indeed, representative.

Q. Do you consider yourself an expert in pathology?

MS. FITZPATRICK: Objection.

THE WITNESS: I do not.

BY MR. SNELL:

Q. On how many occasions did you speak with these pathologists?

A. Probably four or five.

Q. When you placed the PROLENE® polypropylene slings in women for stress urinary incontinence, did you place the sling through the vagina?

MS. FITZPATRICK: Objection. Form.

THE WITNESS: I mean, you

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have to. I'm not sure I understand the question. They all get placed through the vagina.

MR. SNELL: When are we going to have his C.V.?

MS. FITZPATRICK: I'm waiting for it. I should have it, hopefully.

BY MR. SNELL:

Q. In your report, you talk about meetings that you had with Dr. Petros?

A. Oh, yes.

Q. When you met with Dr. Petros, were you aware of whether or not he had looked at using alternative materials for the slings like GORE-TEX® or Mersilene?

A. No, I don't -- I don't really remember any particular conversations with him about the mesh itself. It was more about the concept -- the concept and technique of placing it and the physiology and pathophysiology.

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There were no discussions about mesh characteristics and things like that.

Q. Did you discuss what's commonly referred to as the Integral Theory?

A. Yes.

Q. Did you discuss the investigations or any analyses that Dr. Petros had done in formulating the Integral Theory?

A. Yeah, I think we discussed a lot of the physiology and pathology. We did not -- I did not review papers and data with him.

It was more about how -- trying to understand the way the pelvis works and the way -- and the interaction between the support structures of the urethra and sphincter and the support structures of the rest of the vaginal contents.

Q. Do you believe that the Integral Theory is correct?

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A. I shudder to say this in public, after all my conversations with him and reading it, I still don't understand what the Integral Theory is.

And I'm serious. I don't mean that in any disparaging way.

Q. I believe Dr. Petros gave the Ulf Ulmsten lecture last year in Washington, D.C.

My question to you is, did you attend that meeting?

A. I did not.

Q. When is the last time you saw or spoke to Dr. Petros?

A. Oh, my. I guess ten or fifteen years ago.

Q. So, in your opinion -- let me ask you a question or two.

It says, The Gynecare TVT should not have been designed for placement in a surgically contaminated field.

And you cite to a paper by Culligan, Bacterial County Counts During

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Vaginal Surgery.
What's your methodology for that statement?
MS. FITZPATRICK: Objection.
THE WITNESS: I think you're taking it out of context. I do remember that the caveat was without proper -- I'm paraphrasing -- without proper studies to show that it's safe.
BY MR. SNELL:
Q. Is there a difference between contamination and infection of the mesh?
MS. FITZPATRICK: Objection.
THE WITNESS: The short answer is yes. But I think it's more complicated.
Contamination leads to -- contamination isn't infection, but without -- but contamination is a prerequisite, to a certain extent, of getting an infection. If there's no bacteria in the wound,

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you can't get an infection.
But if there is contamination, it doesn't mean that everybody will get an infection.
BY MR. SNELL:
Q. How do you define "contamination"?
A. It's the presence of bacteria where there shouldn't -- in what's supposed to be a sterile wound.
Q. The vagina has normal occurring bacterial flora, right?
A. Yes.
Q. Do you define contamination by the level of bacterial count?
MS. FITZPATRICK: Objection.
THE WITNESS: Well, it's not how I define contamination, it's what the experts in infectious -- in wound care -- in surgical -- I'm trying to think of the proper word -- surgical sterilization of an operative site define it.

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And my understanding is that 30 -- you know, well, I know for sure that it's -- the wound is supposed to be sterile. And I'm sure there's a certain level -- there may be a certain level of bacteria that they still consider sterile.
But by their own definition, the vagina cannot be sterilized completely for an operation, whereas the abdominal cavity can be, for example. So the consequences -- well, I think that answers the question.
BY MR. SNELL:
Q. Do you consider yourself an expert in infectious disease?
MS. FITZPATRICK: Objection.
THE WITNESS: No, I do not.
BY MR. SNELL:
Q. I want to hand you the Culligan paper you cited in your report.
MR. SNELL: She's going to

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hand it to you.
- - -
(Whereupon, Exhibit Blaivas-2, Culligan Paper, was marked for identification.)
- - -
BY MR. SNELL:
Q. You recognize this as the paper you cited?
A. I do.
Q. So here contamination was defined as greater than or equal to 5,000 Colony-forming units per ML.
A. Uh-huh.
Q. If you look at the results, you will see there were various surgeries done in connection with this paper?
A. Can you refer -- in the results section?
Q. Results section, first paragraph, very bottom two lines.
And that, 23 tension-free vaginal tape suburethral slings took place --

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A. I'm sorry, can you tell me where you are?
Q. Do you see that 23 tension-free vaginal tape suburethral slings were placed?
A. Yes.
Q. And there were other operations done concomitantly.
Do you see that?
A. I do.
Q. You understand that none of these patients developed any infections?
A. I see no -- nothing in here that says how long the patients were followed. I've seen mesh infections ten years after surgery. I don't think you can conclude anything on the basis of not even mentioning the follow-up, the length of follow-up, whether the patients were infected or not.
MR. SNELL: Move to strike as nonresponsive.
MS. FITZPATRICK: Objection to that.

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BY MR. SNELL:
Q. My question was simple and it wasn't about follow up.
It was, you're aware that none of these patients developed infections?
A. I would categorically say that I am not aware that none of them got infections.
Q. There can be infections with non-mesh stress incontinence surgeries like the Burch, correct?
A. Yes.
Q. There can be infections with autologous fascial sling surgeries, correct?
MS. FITZPATRICK: Objection.
THE WITNESS: Yes.
I will say they are very different kinds of infections, though. But, yes.
BY MR. SNELL:
Q. And how do those infections occur in the non-mesh stress incontinence

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surgeries?
A. Presumably by contamination. But I'm not aware, ever, of there being a contamination -- an infection of a pubovaginal sling. All the infections in slings have been superficial wound infections or sometimes deep wound infections.
But almost never is there an infection of the sling itself.
Q. When the fascia lata is stripped from a woman to make an autologous sling, can there be an infection at that secondary surgical site?
A. Sure.
Q. What's the rate of infection at secondary surgical sites for fascia lata harvest?
A. I have no independent knowledge. It's not something I ever researched. I don't do that operation.
Q. What is the rate of nerve injury following fascia lata harvesting?

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A. Injury to the -- I don't know.
Q. What's the rate of postoperative pain following fascia lata harvesting?
A. I don't know.
Q. What's the rate of wound complications following an autologous rectus fascia sling placement?
MS. FITZPATRICK: Objection to this line of questioning.
THE WITNESS: At most, I would say the low single digit percents.
BY MR. SNELL:
Q. So less than ten percent?
A. Oh, yes.
Q. And where do those wound complications occur in the autologous rectus fascia sling placement?
A. I would say almost exclusively in the superficial abdominal wound or rarely in the -- very rarely in the retropubic -- in the retropubic

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space.
Q. Am I correct that you need to do both a suprapubic incision as well as vaginal incision in order to carry out a pubovaginal sling?
A. Yes.
Q. Can there be wound complications to the vaginal incision following the autologous fascial sling?
A. I mean, honestly, I can't ever remember seeing one in over 2,000. I mean, I suppose there can be, but they're not common. They're very rare.
MR. SNELL: Let's take a break. We've been going for about an hour and five or ten.
- - -
(Whereupon, a brief recess was taken.)
- - -
BY MR. SNELL:
Q. Earlier, Doctor, you, in the context of my question about what risk would you discuss with your patients with

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regard to placing a PROLENE® polypropylene sling for stress incontinence, you identified two categories, those that can significantly affect lifestyle and then you said, and then those that are rare and inconsequential and do not really come into the decision process.
Do you recall giving that testimony?
MS. FITZPATRICK: Objection.
THE WITNESS: I do.
BY MR. SNELL:
Q. My question for you is, what are those rare and inconsequential potential complications you were referring to?
A. Death, for one. I mean, I tell people -- unless I think there's -- unless I think there's a risk of death that should be considered, and I -- you know, if it was a 1 in 100 or 1 in 200, that's a risk that should be considered. So I would say death.

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And, again, when I give patients informed consent, I'm talking about when I'm the surgeon. So I tell them it's theoretically possible to develop a fistula and it's theoretically possible to develop a urethral obstruction and, I guess, a complication from the anesthesia; I mean, if it's spinal you can -- rarely a person can get an abscess or something or even be paralyzed.
But I tell them that those things happen so rarely that if it were me, I wouldn't take them into consideration in making a decision for or against the surgery.
Q. Another study you cited on the infection issue, I'll give it to you, it's the Vollebregt paper.
- - -
(Whereupon, Exhibit Blaivas-3, Vollebregt Paper, was marked for identification.)
- - -

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BY MR. SNELL:
Q. What was your methodology in selecting this paper?
A. I didn't use a methodology, per se, other than a literature search about -- I was prompted by the Culligan article, which -- and I just looked to see if there was -- I don't remember if this was -- it could have been cited by him, but I just would have asked my assistant to do a search and find these other articles that look at bacterial contamination of wounds and things.
Q. Who is your assistant who would have done these searches for you?
A. Oh, God. I mean, honestly, there are so many I couldn't -- I couldn't tell you. Because at the -- we were doing -- we have a lot of different research projects going on, and one of them was on infections, not necessarily mesh infections but just infections. And I had, you know, had them doing a huge literature search.

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And what they might have done is they might have been searching something else and come across stuff like this.

Q. I take it you weren't there when they were doing these searches?

A. No.

Q. You don't know the precise methodology these assistants used in caring out the research?

A. I don't think there is --

MS. FITZPATRICK: Objection to the term "methodology."

THE WITNESS: I'm quite sure there isn't a precise methodology. This was sort of a casual -- a casual request.

BY MR. SNELL:

Q. You'll see on the first page of this paper -- this was a paper about prolapse implanted mesh, you understand that?

A. Yes.

Q. Not stress incontinence

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slings, correct?

A. Uh-huh.

Q. Is that a yes?

A. Yes.

Q. On the very first page, on the right column in this paper you cited on infection, it says, Currently, the so-called type 1 macroporous monofilament polypropylene mesh shows the lowest risk of infection and erosion and is, therefore, widely used.

Did I read that correctly?

A. I'm sorry, where is it?

Yes, I just saw it -- no, I didn't. Where are you?

Q. On the first page.

A. I see where it says that, yes.

Q. And it also says, The use of tension-free Type 1 polypropylene tapes in incontinent surgery has been shown not to be associated with a significant risk of mesh-related infections.

Do you see that in this

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paper you cited?

A. Yes, I see it.

Q. And you agree with that statement?

A. No, I agree that that's what the paper says. I agree that you read it correctly.

Q. Of the polypropylene midurethral slings, is it your understanding that the TVT has been studied the most of all of those slings?

A. I know it was when that last -- that question came up. But I haven't at looked at it specifically since.

I mean, it's in my -- I'm sure part of it is in the mesh review article that we did, but I didn't look at it -- I haven't looked at the data with that in mind, so I really have no comment on it.

Q. You mentioned the mesh review article.

And that's the one, Safety

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Considerations for Synthetic Sling Surgery?

A. Yes.

Q. Do you have a copy of that?

A. Not with me.

MR. SNELL: Here, I'll give you a copy.

MS. FITZPATRICK: Do you have another copy of that?

MR. SNELL: I don't think I do, unless Paul does.

BY MR. SNELL:

Q. Go to Page 5 of this article.

And you're a -- you call it a senior author on this paper?

A. Yes.

By Page 5, you -- there's page numbers at the bottom.

Q. Yes, sir.

MS. FITZPATRICK: Have you marked this as an exhibit?

MR. SNELL: Let's go ahead and mark this as an exhibit.

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- - -
(Whereupon, Exhibit Blaivas-4, Article, Safety Considerations for Synthetic Sling Surgery, was marked for identification.)
- - -
BY MR. SNELL:
Q. So, Doctor, you're at Page 5?
A. I am.
Q. And in your review paper, you wrote -- and I'm on Page 5 at the top paragraph.
MS. FITZPATRICK: When you say Page 5, I start at 481.
THE WITNESS: That's what I'm saying, these are actually numbered 1, 2, 3, 4, 5 and this, for whatever reason, is completely different page numbering.
I'm the same as you.
MS. FITZPATRICK: My 485 is your Page 5. Good enough.

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Thanks.
BY MR. SNELL:
Q. It says, We estimate that bowel perforation and serious infections have a combined incidence of about 0.1 percent.
Correct?
A. Where are you now?
Q. Page 5, top right column.
A. Yes.
Q. And then there are citations to papers numbered 117 to 134, correct?
A. Yes.
Q. And the combined estimated rate of bowel perforation and serious infection, you were referring to synthetic midurethral slings?
A. Yes.
Q. Do you consider a serious infection rate of -- strike that.
When you wrote that "we estimate that bowel perforation and serious infections have a combined incidence of about 0.1 percent," did you

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attempt to ascertain what was the rate specific to serious infection?
A. No. But we decide -- no. But I think that -- no, is the answer to your question.
Q. And when you say "serious infection," what do you mean by that?
A. Really, we were talking about life-threatening sepsis or infections that require -- retropubic infections that are either life threatening or require multiple operations to remove.
Some of them were, like, thigh infections -- just for example, thigh infections after transobturator slings were used that required three, four, five operations to deal with the infection and remove the mesh.
So these were the most serious infections, is what this was talking about.
Q. 0.1 percent, you would consider that rare?

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A. Yes.
Q. The thigh infection you mentioned with the transobturator slings, is it correct that the retropubic sling, like a TVT, has a lower risk of thigh infection than transobturators?
A. I would say it has no risk of thigh infection, or just about no risk.
But, also, there were serious kinds of infections. Again, life-threatening sepsis are the kinds of things we were talking about, not just -- yeah, that's what we were talking about.
Q. On the first page, top right, where it says, Furthermore, an analysis of 7,200 case logs submitted by American urologists for their certifying credentials in 2013, 83 percent of operations performed for incontinence in women were midurethral sling implantations.
Is that correct?
A. That's what it says, yes.

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Q. Why did you cite to that paper?
A. Why?
Q. Yes.
A. Because it gave some sense of how often midurethral slings -- synthetic midurethral slings are done in the U.S.
Q. Is it your understanding that American urologists use more synthetic midurethral slings for the treatment of stress incontinence than the Burch colposuspension?
MS. FITZPATRICK: Objection.
THE WITNESS: Yes.
BY MR. SNELL:
Q. Is it your understanding that American urologists use synthetic midurethral slings, like TVT, to treat stress urinary incontinence more often than the autologous pubovaginal slings?
A. Yes.
Q. Is that still true today?
A. I believe so.

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Q. Do you know the percentage of American urologists who, like you, use the autologous fascial sling as their primary stress incontinence surgery?
A. I do not.
MS. FITZPATRICK: Objection.
BY MR. SNELL:
Q. A little further down on that page, it says, Midurethral sling implantation is a minimally invasive, easy to perform procedure that is usually completed in under half an hour, and compared to traditional native tissue repairs enables a much faster recovery, with less postoperative morbidity than either the Burch colposuspension or autologous fascial slings.
Do you see that, that you wrote?
A. Yes. That was perioperative morbidity. Yes.
Q. And when you wrote that sentence, you were including the TVT Ethicon sling in that consideration?

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A. Yes.
Q. When you state that the TVT is "minimally invasive," what do you mean by that?
A. Well, you left out the -- I don't know if you left it out, but its predicated by, in theory. It starts with, The appeal of such procedures is obvious in theory.
And I was -- the sentences that you read related to the theory. So I don't think it's minimally invasive. But that's what it's billed as.
Q. So do you believe that autologous sling is minimally invasive?
A. I do not.
Q. When you use the term "minimally invasive," what do you mean by that?
A. The implication of minimally invasive is that it's -- that it doesn't require a lot of surgery and that it's safe, and that -- the whole context is that it takes a shorter amount of time,

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smaller incision and safe.
And the -- and easy to do. And that's what the -- to me, that's what the connotation of minimally invasive is.
And I don't think it's that, in taking those things into consideration, that it's minimally invasive; although it does use a smaller incision, it can be done quickly.
But I think the potential invasion of the body, when it can cause major complications, makes it not so minimally invasive.
Q. You write --
A. Excuse me, potentially not so minimally invasive.
Q. You write, The effectiveness of this approach remains unchallenged, though.
Correct?
A. Correct.
Q. What did you mean by that?
A. I mean, I think the efficacy, every study comparing

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midurethral -- midurethral slings to the gold standard of at least autologous sling shows comparable efficacy. And I do believe that that is true, that the chances of a successful outcome with respect to improvement in stress incontinence is comparable.

Q. You write, Numerous trials have shown midurethral slings to be as effective as the autologous fascial sling.

And that's what you were just referring to?

A. Yes.

Q. And you also say, And Burch colposuspension.

Correct?

A. Yes.

Q. Is that an opinion you hold?

A. No. I think the Burch -- my own opinion is that the Burch is not as -- is not as effective an operation as the other two. But it's not -- the peer-review literature does not reflect

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that.

Q. And you say that -- that this is based on moderate and/or high quality of evidence?

A. Yeah. I think the quality of evidence for efficacy is -- I wouldn't call it high quality, but I think it's much improved over what it used to be.

Q. Well, here you wrote that the quality of evidence was moderate and/or high.

Why did you use those terms?

A. Well, this is a bunch of authors here and we agreed on the terminology. You asked my opinion, and my opinion, I would have been happier with moderate.

There is some -- there are some high quality papers and, overall, the quality of the evidence today compared to 20 years ago is much improved.

What's lacking, I might add, is that the follow-up is inadequate.

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Q. What do you mean by that?

A. There aren't good long-term follow ups for these, in my judgment.

Q. You're aware that there are numerous studies that assess TVT at five years or more duration?

A. I'm not. I'm aware of five studies that -- five studies that go -- six studies that go more than five years. And considering that millions of these operations have been done, I don't think a total of -- I think there are -- we found eleven studies of five years or more. That's hardly numerous studies of long duration.

Q. Who did the search that only came up with these eleven studies of five years of duration or more?

MS. FITZPATRICK: Objection.

THE WITNESS: The actual search was -- the people that did the search were -- the actual search, I mean, the computer search, were Gabe Mekel, Mike

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Stern, Billah and Kola, the middle authors.

BY MR. SNELL:

Q. And do you know what methodology they used to try to ascertain how many long-term TVT studies there were?

MS. FITZPATRICK: Objection.

THE WITNESS: We didn't use --

MS. FITZPATRICK: -- to the term "methodology."

THE WITNESS: -- methodology to determine that. We used methodology to find the studies. Then we found the studies, excluded -- I mean, the methodology is all in the paper.

We found a large number of studies. They had to meet certain criteria for inclusion.

And then we had the -- we found the ones that met the criteria for inclusion. And then

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we -- and then, thereafter, we narrowed them down to what we thought were acceptable studies, and we came up with those 11.
BY MR. SNELL:
Q. Do you consider five years duration or more a long-term study?
MS. FITZPATRICK: Objection.
BY MR. SNELL:
Q. In the field of stress urinary incontinence clinical literature?
A. No, I don't. Say that again. I may have misheard you. Please repeat the question or read it back.
Q. Let me ask you this, I'll ask it a better way.
What do you consider a long-term study that's looking at a stress urinary incontinence surgery?
A. I would want to see about a decade.
Q. How many decade-long prospective clinical studies are there on the pubovaginal sling?

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MS. FITZPATRICK: Can you read that question back?
- - -
(Whereupon, the court reporter read the following part of the record:
"Question: How many decade-long prospective clinical studies are there on the pubovaginal sling?")
- - -
MS. FITZPATRICK: Objection.
THE WITNESS: I'm not aware that there are any. I don't know.
BY MR. SNELL:
Q. How many ten-year -- strike that.
How many decade-long studies are there that evaluate the pubovaginal sling retrospectively?
MS. FITZPATRICK: Objection.
THE WITNESS: I mean, I can make this pretty quick. I don't think there are any decade-long

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studies, and if there are, there are very, very few.
BY MR. SNELL:
Q. Would it be correct that there are more long-term studies for TVT as compared to the pubovaginal autologous sling?
MS. FITZPATRICK: Objection to the use of the term "long-term."
THE WITNESS: I am not sure. But there's few -- there are so few of both, from my perspective, to be pretty meaningless.
I mean, these are quality -- stress incontinence is a quality-of-life operation. It's done in people mostly in their early 50s who are expected to live to -- nowadays to, probably, 100. And to say that a five-year study is long-term, to me, is not rational.
I mean, you -- if you're

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having an operation, you'd want to know that it was going to last more than five years, or at least know how long it's going to last.
BY MR. SNELL:
Q. The pubovaginal sling, autologous sling, has been around since around the first decade of the 1900s, as I understand it.
Is that consistent with your knowledge?
A. 1900s? No, no.
Q. 1907?
A. No. That was a very primitive form. I mean, to -- to preempt your question, I think autologous sling sort of gained momentum in the mid to late 1990s.
I mean, before that, it was done almost exclusively for people who were considered hopeless failures of other conditions.
Q. Do you have an understanding or knowledge as to why there are no ten

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year or more duration studies for the autologous fascial sling?
A. Yeah. I think prospective studies are really, really hard and expensive to do. I mean, I think it's a generic problem for anything. I they're very, very hard to do. No more difficult for the autologous than for the synthetic slings, but.
Q. What is the longest term follow up that you're aware of in the medical literature for the autologous fascial sling?
A. I don't know about the literature, but I have personal follow up of 27 years, a patient that I followed.
I think in the literature, if I'm not mistaken, but I could be mistaken, one of my papers has a -- is 15 or 20 -- maybe 15-plus year follow up.
But, again, it's not on -- not a series of 15, but people that were followed that long. I think -- I don't know, I think -- I don't know of any

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papers that have a minimum follow up of ten years.
Q. Do you know how many randomized control trials have assessed the pubovaginal sling, autologous pubovaginal sling at a duration of five years or more?
A. I don't think there are any.
Q. What are the potential benefits with using a TVT?
A. I missed that one word. What benefit?
Q. The potential benefits from using a TVT.
A. The potential benefits are what I alluded to -- what we alluded to in the paper; that it can be done in a short time with a negligible-sized incision with a -- let me just read it -- with a faster recovery and less perioperative morbidity.
Those are the theoretic benefits.
Q. Is it desirable to surgeons

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to have shorter operative times?
A. Yes.
Q. Is it desirable for the potential risk to the patient to have a shorter operative time?
A. Only if the shorter operative time is accompanied by other safety features.
Q. Is it correct that the longer a patient is undergoing an operation, there is an increased risk to that patient?
A. In a general way. But I don't think that applies very much to these operations, because neither -- none of them take a very long time.
But, as a general rule, yes. But I don't know that the difference between a half hour and an hour and-a-half makes any difference.
Q. Is it desirable to surgeons doing stress incontinence surgery to use the smallest incision as possible to accomplish the job?

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MS. FITZPATRICK: Objection.
THE WITNESS: Yes, if it accomplishes the job without increased attendant risks because it is small.
BY MR. SNELL:
Q. Earlier, you testified, and you, I believe, wrote this in your report, that you recognize that the efficacy of, like, the TVT is on par with the pubovaginal sling, correct?
A. Correct.
Q. How does the TVT work as well as a pubovaginal sling?
A. I'm not sure I understand the question.
Q. How is it that the TVT works, it has the comparable same efficacy as the autologous pubovaginal sling?
MS. FITZPATRICK: Objection to form.
THE WITNESS: Because it's a very similar mechanism of action,

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it's just replacing the sling with -- the autologous sling with synthetic.

So -- I'm not sure I understand your question. Unless I just answered it.

BY MR. SNELL:

Q. You did.

I believe in this paper, the citation we were just looking at, Number 8 is Ogah -- Ogah Cochrane review.

That's a paper you've read?

A. Yes, I have.

Q. What level of evidence is an -- what level of evidence is a Cochrane review?

A. Well, a Cochrane -- I need to see the paper to remind me. But, basically, they classify --

Q. Actually, I have the one you cite. I'm sorry, I didn't mean to talk over you. Let's mark this, so you can have it.

- - -

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(Whereupon, Exhibit Blaivas-5, Ogah Cochrane Review, was marked for identification.)

- - -

BY MR. SNELL:

Q. So Citation Number 8 in your paper is this Cochrane review, the short version Cochrane review from 2011 by Ogah, Cody and Rogerson?

A. Yes.

Q. So what level of evidence is a Cochrane review, such as the Ogah paper you cited?

A. I'm looking to try to see.

This states that they did -- they reviewed 62 trials and that the quality of evidence was moderate for most trials.

Q. Have you heard of the Oxford Levels of Evidence Pyramid?

A. I'm not familiar with the particulars.

Q. Well, do you know what the levels of evidence are as it pertains to

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the medical literature?

A. Only in a very, very general way. I don't -- I mean --

Q. Do you understand systematic reviews --

A. Again, in a general way.

Q. -- and Cochrane reviews to be a higher level of evidence than individual randomized control trials or not?

A. I understand that they're perceived that way, but I personally find sort of intellectual and methodological flaws in the reasoning. The practical application of those things.

So I understand it in concept, but I don't agree with all of them.

Q. Do you believe that randomized control trials are, in general, a higher level of evidence than retrospective cohort studies?

A. I think it depends upon the level of the -- it depends on the metrics

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of the outcome tools.

So as a general rule, I can't answer that question because you can have a very, very high quality randomized trial, but the outcome measures may not be sufficient to answer the questions adequately.

And I think -- I'm not nitpicking, I think that's a common problem in the medical literature. This is coming from someone that was the editor in chief of a major journal for 25 years or so. So it's not a -- it's not a callous statement.

Q. Have you read the most recent Cochrane review that came out this summer by Cody?

A. I don't know if I did or not.

Q. How would you characterize the overall quality of evidence for autologous pubovaginal slings?

MS. FITZPATRICK: Objection.

THE WITNESS: I would say

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moderate to poor at best, or poor to moderate at best. I think there are some studies -- well, you asked me in general. In general, I would say poor.

BY MR. SNELL:

Q. You were one of the members who was involved in evaluating the medical literature in connection with the American Urological Association's most recent stress incontinence guidelines, correct?

A. I was.

Q. And in connection with the formulation of the -- can I call them AUA guidelines?

A. Sure.

Q. In connection with the formulation of the AUA guidelines, did you assess the overall quality of the medical literature?

A. We did.

Q. In the assessment of the overall quality of the medical literature

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for the AUA guidelines that you participated in, did you and the other authors of that guideline take an evidence-based approach to your analysis?

A. We did.

Q. And what is taking an evidence-based approach to an analysis of stress urinary incontinence surgeries?

A. Well, we needed to -- the mandate we were given was to use an evidence-based approach which had specific guidelines and requirements for each of the things that we did. So the short answer is yes.

Q. And one of the conclusions of the AUA stress incontinence guidelines that you participated in was that the polypropylene midurethral slings, like TVT, were a suitable surgical option for stress urinary incontinence, correct?

A. That's correct.

But another conclusion was that the quality of evidence, overall, was very poor.

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Q. And that's across the board?

A. Yes. I'm sorry to say. But it calls into question all of the claims.

Q. Have you ever -- I don't know if I asked you this question specifically. I don't think I did.

Have you ever done an analysis by which you have attempted to ascertain the number and body of literature on, specifically, the TVT Ethicon retropubic device?

A. Separately?

Q. Yes, sir.

A. No.

Although, in fairness, particularly in the early part of the century, for a long time, for part of that, the TVT was the only retropubic device. So, by default, you know, most of the studies would have been on that.

Q. For the retropubic sub -- strike that.

For the retropubic midurethral slings, it's your

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understanding that if you look at the volume of published clinical studies on TVT, it is far beyond that published on other retropubic slings that use polypropylene?

A. You know, that's my general impression, but I couldn't get more specific than that. And within the more current literature, I don't even know if that's true. I just didn't separate it out in my mind like that.

Q. Do you view all midurethral slings as being the same in your mind?

A. No, not at all. I mean, I think they have particular -- you know, there are different ergonomics of trocar passing that is different, sling compositions and -- yeah. I mean, just those two things alone, I think, are very important.

But, I should say, there's enough in general that they are more alike than they are dissimilar.

Q. And the Ogah Cochrane review

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you were just looking at the results --
A. Uh-huh.
Q. -- where you talked about the quality of evidence.
The next sentence says, Minimally invasive synthetic suburethral sling operations appear to be as effective as traditional suburethral slings.
Do you see that?
MS. FITZPATRICK: Sorry, where are you again, Burt?
THE WITNESS: Yes, I do.
MS. FITZPATRICK: Okay.
BY MR. SNELL:
Q. But with shorter operating time and less postoperative voiding dysfunction and de novo urgency symptoms.
Do you see that?
A. That's what it says. I don't agree with those conclusions, but that's what it says.
Q. And the methodology used in the Cochrane review, they found eight

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trials that met their methodology, do you understand that, on that point?
A. Yes.
Q. Do you disagree that in those eight trials that the synthetic midurethral sling showed less postoperative voiding dysfunction than the traditional suburethral sling?
A. I mean, I'd need to see the data more. But if you look at -- just, for example, if -- I'm just reading something here.
I mean, they cite -- I'd have to see the data. I don't know.
But I don't agree with those findings, no matter -- let me just look at this for a second.
I'm going to retract my statement. I'd have to look at this in more detail to answer your question.
I agree with the first part, that they're just as effective. I don't -- and the less postoperative voiding dysfunction, I mean, I think this

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is combining transobturator with retropubic slings, the sentence you just read.
So I'd really need to look in more detail about it, to determine whether or not -- what my answer is.
Q. In your AUA guidelines for stress urinary incontinence, you found less voiding dysfunction and urge symptoms --
A. I think that was --
Q. Let me just get the question out.
A. Yes.
Q. -- with the midurethral slings than you did with the traditional autologous slings that were not anchored to the bone, correct?
A. That conclusion was based on historical studies versus modern studies.
So the difference is there weren't any contemporaneous -- there were few contemporaneous studies in there. So they were comparing the way we do

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midurethral slings now, which is with tension free, with the way they did autologous slings in the '80s -- in the '80s and '90s, which was not tension free. There were many surgeons who thought, in those days, that an autologous sling needed to be placed with tension.
So I think, to me, it was comparing apples and oranges. So I don't -- and the -- I believe the current studies that used appropriate and comparable techniques would find that there's probably no difference. In fact, in my judgment, I think properly done autologous studies of the bladder neck actually have less of those complications than midurethral slings. But few people do the surgery that way.
Q. But the answer to my question is, yes, that was a finding in the AUA guidelines?
A. Yes, I said that. I did answer that.

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Q. And when you mention current studies on the autologous fascial sling, what current studies are you referring to?
A. I mean, there was just a study by -- I don't remember who the primary author was, the first author was. But there was a study by Roger Dmochowski's group. There's a study by Eric Rovner comparing synthetic slings to -- synthetic slings to autologous fascia slings.
And my recollection is that the findings were comparable. But I would really -- I would need to see those papers to answer your question. I mean, to answer with certainty.
Q. You didn't cite to Dr. Dmochowski's paper or Eric Rovner's paper in your expert report, correct?
A. No.
Q. I'm not correct?
A. Correct, yes.
Q. Oh, thank you.

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A. I thought you said you didn't. Oh, okay.
Q. Let's just -- we have a double negative and that's my bad.
How about we make it this way: Did you cite to either Dr. Dmochowski's paper or Dr. Rovner's paper in your expert report?
A. I did not.
Q. Thank you.
MR. SNELL: Let's take a break.
- - -
(Whereupon, a brief recess was taken.)
- - -
BY MR. SNELL:
Q. In your paper that was published this year on midurethral slings, we were discussing the long-term studies that were found, correct?
A. Yes.
Q. Table 1 says, Long-term follow-up duration of more than five

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years, studies --
A. Yes.
Q. -- of midurethral slings effectiveness.
Do you see that?
A. Yes, I do.
Q. So there are 11 studies mentioned here in Table 1, correct?
A. Correct.
Q. Were there more than 11 studies found that fulfilled these criteria of a follow-up duration of five years or more but for some reason did not make it into Table 1?
MS. FITZPATRICK: Objection.
THE WITNESS: I honestly don't know. I don't think so, but I don't know for sure. I could find out.
BY MR. SNELL:
Q. The sixth paper down is a paper by Serati, 2013.
A. Yes.
Q. It looks like that involved

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transobturator slings.
Do you see that?
A. Correct.
Q. And that had a duration of follow up of 60 months?
A. Yes.
Q. Were you aware that there's a paper by Serati on the TVT retropubic device with a follow up of greater than ten years using very similar methodology to this paper that you cite regarding transobturator slings?
MS. FITZPATRICK: Objection to form.
THE WITNESS: No.
BY MR. SNELL:
Q. That's a paper you've never read?
MS. FITZPATRICK: Objection to form.
Can you identify the paper specifically for him?
MR. SNELL: Yes.
BY MR. SNELL:

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Q. The ten-year plus Serati paper on the TVT retropubic device, is that a study you've read?
A. No.
MS. FITZPATRICK: Do you have a copy of it? Or a cite to it or something like that so we have a clear record of what we're talking about?
MR. SNELL: I'm sure we can get a cite.
THE WITNESS: Or the year it was published?
MS. FITZPATRICK: Or a copy of the paper, too.
MR. SNELL: I'm not going to ask him about something he hasn't read, so --
MS. FITZPATRICK: I just want to make sure that you're both talking about the same thing. So he needs to see what the paper is and say, yes, I've read it or no, I haven't.

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THE WITNESS: Can you repeat that?
MS. FITZPATRICK: I said I want him to show you the article so you can say yes, I've read it or no, I haven't, instead of just asking.
BY MR. SNELL:
Q. In Table 1, there is no ten-year TVT study, we can agree on that, correct, by Serati, at all?
A. Correct.
Q. And you don't know whether whoever did the searches came across it and purposely did not put it in there for some reason or another?
MS. FITZPATRICK: Objection.
THE WITNESS: It is -- I would think that's highly, highly unlikely that they came across it and didn't include it.
I mean, I don't know, it might have not met our search criteria. I don't know.

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BY MR. SNELL:
Q. Doctor, I don't have a printout, but I'll show it to you. Tension-free Vaginal Tape for the Treatment of Urodynamic Dynamic Stress Incontinence: Efficacy and Adverse Effects at 10-Year Follow Up, published in the European Urology Journal, Volume 61, 2012.
Have you read that study?
A. Can I see it?
MS. FITZPATRICK: Can we get a printout of that?
MR. ROSENBLATT: Yes.
MS. FITZPATRICK: That would be great. Thanks.
BY MR. SNELL:
Q. Can I come look over your shoulder, because I don't have a copy either?
A. Sure.
Do you know why it's doing that?
Q. I think the connection is

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very slow.
A. Oh, you're getting this off the --
Q. Yes. It's off the Internet.
A. This is what I want to see.
No, I don't remember seeing that. And I want to just check one thing here.
MR. SNELL: Do you have a copy of this paper, Paul?
MR. ROSENBLATT: No. I can get one made.
MR. SNELL: We'll come back to that, Doctor.
THE WITNESS: Okay.
BY MR. SNELL:
Q. As far as you recall, you don't remember reading that ten-year paper by Serati at all?
A. No. Which doesn't mean I haven't seen it. And I may have it -- I may have seen it.
Q. If you'd go to Page 4.
A. May I just take one second?

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Q. Let's go off the record, then.

- - -

(Whereupon, a discussion off the record occurred.)

- - -

THE WITNESS: In the Nature review article, we originally included the methodology by which we selected and rejected papers and in the -- sorry.

I just -- we can go off the record now. They moved it.

What I was going to say is that --

MS. FITZPATRICK: This should be on the record.

THE WITNESS: I was looking for the search criteria, and the editors took it out of the method section. And I just realized they put it in a box on the side. So I'd like to refresh my memory and look at it.

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BY MR. SNELL:

Q. You're looking at the last page of --

A. Page 21.

Q. Correct.

The last page of the paper, before the references?

A. Yes.

Q. Under the color box that says, Review criteria?

A. Yes.

We're on the record?

Q. Yes. We're on the record.

A. Unfortunately, they edited, because of their journal guidelines, to the point where I can't find the information that I need to see whether or not I would have seen that article or rejected it or not.

So I will not have an independent recollection of whether I saw it or not.

Q. Just so we can agree, though, it says, This says a search was done and they used terms, TVT tension-free vaginal tape, tension free vaginal sling.

Correct?

A. Correct.

Q. And the search was done, limited to human patients, clinical data, correct?

A. Correct.

Q. And this review was done in August 2014?

A. Correct.

Q. And we just looked at the Serati ten-year TVT study, and in the title, it talks about tension-free vaginal tape, correct?

A. Correct.

Q. And it was published in a well-respected European urology journal in 2012.

We saw that, right?

A. Correct.

Q. And it was in human women with ten years or more duration of follow-up, correct?

A. Well, I haven't seen -- I saw the title. I didn't read the -- look at the paper. But in the title it says ten years, yes.

MS. FITZPATRICK: If you're going to ask him questions about the article specifically, can we get a copy?

MR. SNELL: I'm going to get a copy.

BY MR. SNELL:

Q. But as you sit here, you have no idea, then, why that paper did not make it into the table that you reported in your article of long-term five-year studies?

A. That's correct.

Q. And there very well could be other studies of five-years duration, or more, with the TVT that, for reasons unbeknownst to you, do not show up in that table, correct?

MS. FITZPATRICK: Objection.

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Misstates the testimony.
THE WITNESS: Since we found one, it's possible there's another, sure.
BY MR. SNELL:
Q. Right above where you were looking in your article --
A. I'm sorry, on Page -- the last page?
Q. Page 21 in your conclusion section.
A. Yes.
Q. It says, We calculated -- I'm right here.
A. I see where you are.
MS. FITZPATRICK: Can I see? Where are you?
BY MR. SNELL:
Q. We calculated the overall risk of a serious complication or surgical failure to be 12.5 percent.
A. Yes.
Q. That's what you wrote in the paper, correct?

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A. Yes.
Q. Do you stand by that number today?
A. I'm not -- I stand by a number close to that. We did the calculations a couple of different ways, and I would say it's somewhere between 12.5 and 15 percent, as a minimum. So that's in the same ballpark.
I noticed, in my review, that they -- I don't know if it was a typo or what, but one of the numbers was off by a percentage. And let me just see if I can find it.
It says -- the 5.6 percent, we have calculated the minimum risk for revision surgeries for erosion and obstruction alone was 5.6 percent. I think it was 4-point something.
These are small differences that don't have a consequence in the overall interpretation, but there's a discrepancy between that number and a number in the -- in the result section

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and in the abstract that I think may have been a typo, but I'm not sure.
So I stand by the 12.5 to 15 percent as a minimum.
Q. I'm going to ask you a hypothetical.
Would it concern you if there were more than ten other TVT retropubic studies with five-years duration or more that you did not include in that table in your review article?
MS. FITZPATRICK: Objection.
THE WITNESS: I would want to see them. But it -- it would concern me in terms of trying to find out why our methodology didn't pick them up.
But I don't think it would concern me with respect to the overall conclusions simply because five more or ten, more or less, is just infinitesimally a small number compared to a denominator of millions and millions --

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millions of patients that have had slings. So if you add another 500 or 1,000 patients with almost uniformly poor metrics in looking at complications, this paper is about complications, virtually -- we couldn't find any paper that had a good metric for prospectively looking at complications.
So I think that, in my own opinion, the literature is so poor with respect to documenting complications that it would not concern me if we missed another ten papers, except for my own -- the integrity of our own research process and wanting to figure out why.
BY MR. SNELL:
Q. You're assuming that those ten or more papers, hypothetically that you would have missed, would not have methodologically assessed complications?

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MS. FITZPATRICK: Objection.
THE WITNESS: In a rigorous enough way to allow me -- to allow a scientific observer or investigator to make conclusions about the incidence and consequences of complications.
BY MR. SNELL:
Q. Turn to Page 11 of your review article.
MS. FITZPATRICK: Can I see what it looks like, Burt, because I have the different numbering.
MR. SNELL: The very bottom says, Mesh erosion in the bladder. The bottom right says, Mesh erosion in the bladder.
THE WITNESS: Yes.
MS. FITZPATRICK: Okay, great. Thanks.
BY MR. SNELL:
Q. Over the left side.
A. Of the same page?
Q. Same page. Towards the

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bottom where you're talking about different types of mesh.
Do you see that?
A. I do.
Q. You wrote, Type I (knitted monofilament and macroporous polypropylene mesh) is currently considered to be the optimal SMUS -- and that's midurethral sling abbreviated?
A. Yes.
Q. -- mesh material owing to its large pore size greater than 75 microns.
Correct?
A. Correct.
Q. A mesh with a pore size of 75 microns or -- strike that.
A mesh with a pore size of greater than 75 microns is considered macroporous?
A. It is. But some people think it should be larger than that now. But, yes.
Q. And it says, It facilitates

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infiltration of macrophages and fibroblasts, promotes neovascularity and tissue ingrowth, and minimizes the likelihood of infection.
That's what you wrote, correct?
A. Correct.
Q. And the TVT is a knitted monofilament macroporous polypropylene mesh, correct?
A. Correct.
Q. And in the next -- and actually you cite to PROLENE® in your paragraph there, correct?
A. Yes.
Q. And in the next paragraph, you talk about how several manufacturers have designed lightweight meshes.
Do you see that?
A. Yes.
Q. Of decreased density with smaller fiber diameter and larger pores with the intention of preventing stiffness, contraction and

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mesh shrinkage.
You wrote that, correct?
A. Correct.
Q. And then you went on to state, Several published studies purport some benefit of these new materials in patients requiring inguinal hernia repair.
Do you see that?
A. Yes.
Q. However, all of the studies involve small numbers of patients with limited follow-up duration, thus precluding any meaningful conclusions.
That's what you wrote, correct?
A. Yes.
Q. And did you find, in doing any searches, the use of these lighter weight meshes used in women with stress urinary incontinence demonstrating any type of meaningful conclusion?
A. I don't have an independent recollection of that.

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Q. At the top of the next page, it says, Amid Type II mesh (monofilament and microporous) has pores less than 10 microns in diameter.
Right?
A. Correct.
Q. And it says, That are large enough to allow bacterial infiltration but too small for macrophage infiltration, thus infection is more probable and tissue ingrowth is impeded.
Correct?
A. Correct.
Q. That's one of the potential risks of using an Amid Type II mesh?
A. Yes.
Q. And a little further down, you say, Type II to IV meshes, including PTFE mesh, silicone-coated polyethylene or polyester and nonknitted, nonwoven mesh such as ObTape and Uratape have been documented to have a much higher incidence of erosion, 16 to 25 percent, compared with that of Type I meshes (zero

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to 10 percent.)
Correct?
A. Yes.
Q. And that's -- and then you list numerous citations after that, correct?
A. I do, or we do.
Q. In your opinion, should Ethicon's TVT device be significantly changed or modified in its design?
A. Yes, I -- let me think about that for a second.
Yeah. I would say yes. When I say yes, I'm talking about the mesh and the kit, and the implantation kit.
Q. And how should it be significantly changed or modified in design?
A. Well, I have -- I mean, these are personal -- you're asking a personal opinion now.
And my personal opinion is that the -- to start with, the technique

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of passage, the way they are designed for passing the trocar is seriously flawed and based on a theory that is just incorrect. And I think that the surgical technique can and should be changed in a way that I believe would make it much safer, in terms of passage of the instrument and avoiding the bladder and urethra.
So I would change the trocar design. And I would change the, certain aspects of the recommended surgical technique. And the two things together, I think, could make it much safer.
And, yes, I think the mesh should be designed in a way that reduces the possibility of chronic inflammation and erosion and scar contraction.
Q. With regard to the trocar design, what would you change about it?
A. I'm not sure this is the proper venue for me to be redesigning their equipment. I mean, I don't think I can say in words very succinctly what

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needs to be done.
I'd need to -- I told you the general things, the general concerns that I have about it. I mean, I'm happy to if you want me to continue, but without a -- it would be -- I hadn't ever thought about doing this in public. But, I mean, this is my opinion.
MS. FITZPATRICK: And I'm going to object to this whole line of questioning as beyond the scope.
But go ahead, if you'd like.
THE WITNESS: Do I answer?
MS. FITZPATRICK: Yeah.
MR. SNELL: Yes.
THE WITNESS: So I think that the technique that I use for the autologous fascial sling, I've done over -- you know, well over 2,000. And with a couple of exceptions, I've never damaged the bladder or urethra, never perforated the bladder or urethra,

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except for a couple of patients that had multiple, multiple operations of synthetic slings in the same place.

And the reason is, to start with, the technique requires, without exaggeration, an extra maybe five minutes of dissection. And if you dissect into the retropubic space and put your finger in the retropubic space protecting the -- protecting the bladder and urethra, then you can pass the instrument from above instead of through the vagina and you're not doing it in a blinded fashion and you would completely protect the bladder and urethra. And in my estimation, you should almost never get into the bladder or urethra.

And, again, I've never done it, and it's never been -- except for these, I think, two instances.

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So that would eliminate a major cause, in my judgment, of subsequent erosion.

I cited a paper in there, again, by -- I think this was by Osborn, where there's a 26-fold increase, 26-fold increase in the likelihood of subsequent erosion into the vagina or the bladder in patients who have had a perforation of the bladder or urethra at the time of the original surgery.

And, again, in my opinion this is 100 percent, or practically 100 percent preventable. So that's the surgical technique, which is part of the -- you know, part of the procedure.

The second thing is, it makes little sense to me to use this, you know, bottoms-up approach. The bottoms-up approach

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that they use with the trocar passage precludes any protection of the bladder or urethra.

You just have to, for practical purposes, hope that you don't put the trocar into the bladder, the urethra or, even worse, the iliac artery of the obturator, all of which -- every one of those complications has occurred.

And, in my judgment, virtually never occurs, not once, if you use the top-down approach. I think it's not physically possible.

So that's the second point that I would change.

And the third point is that the trocar itself is too big, too thick and too pointed. You know, that trocar gets -- it's very easy to do significant damage to the adjacent structures if the trocar

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goes in the wrong place.

So if you use a much smaller trocar -- I mean, I alluded to the fact before that I use a Stamey needle, which is very thin and very unlikely to do any major damage. And if you pass it from above to below, the chances of injuring any adjacent organ is as close to zero as you can get.

That's it.

BY MR. SNELL:

Q. With regard to your statement that you would dissect more into the retropubic space --

A. Yes.

Q. -- what are the risks attendant with doing more dissection and deeper dissection into the retropubic space?

A. I don't think -- I don't think there's any. I mean, you're doing -- you're doing with your finger exactly the same thing that you're doing

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with a big blunt -- a big sharp instrument.

So whether you do it with your finger or an instrument, you are still going into the same place. I don't think there's any more hazard. I think there's less hazard.

That might not have been your question. Was the question the hazards or additional risks?

Q. Yeah, what's the -- are there additional risks by doing a larger dissection deeper into the retropubic space?

A. I think there are less risks.

Q. Does a larger incision have a higher risk of erosion?

A. Yes, it probably does. But this isn't a larger incision.

Q. Are you saying the TVT trocar is equivalent in size to your finger, and the incision -- strike that -- the dissection you would make up

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into the retropubic space?

A. Yeah, I don't -- we're talking about such a small incision that it's inconceivable to me that it would make much difference.

I would have to check my finger against the size of the trocar, but it's not very different. And my finger doesn't have a point at the end of it.

Q. Are there any clinical studies using midurethral slings that evaluate whether less dissection -- strike that.

Are there any clinical studies in midurethral slings that demonstrate that there is less risk when you do a larger dissection into the retropubic space?

A. I don't know.

Q. You mentioned the -- you would prefer to do a top-down approach as opposed to a bottom-up approach?

A. Well, yeah. Your specific

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question was, how do I think it could be improved. And I think that would be a great improvement.

Q. Do you know whether or not a top-down approach for TVT was ever offered or made available to surgeons?

A. I think -- no, I don't have an independent recollection.

Q. Do you know whether your opinion that proceeding from the top down as opposed to bottom up would lead to less risk of urethral perforation and other complications been has tested in any randomized control trials?

A. The technique that I'm talking about has not, to my knowledge, been done for this, so it hasn't been tested.

But it's been done thousands of times by me and other people that do autologous slings.

Q. Do you have that Ogah Cochrane review that we were looking at earlier that you cited in your review

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paper?

A. Yes.

MS. FITZPATRICK: Which one is this?

BY MR. SNELL:

Q. What exhibit is that, Doctor, the number?

A. Exhibit 5.

Q. You see this Ogah Cochrane review you cite to? I just want to show you where I'm at.

A. Yes.

Q. They did assess a bottom-to-top route compared with a top-to-bottom route, correct?

A. Yes.

Q. And they found the bottom-to-top route -- and that's the TVT retropubic route, correct?

A. Yes.

Q. -- was more effective than a top-to-bottom route, correct?

A. That's what it says.

But if you look at the -- I

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mean, the actual relative risk was so negligible, number one.

Number two, this is not the technique I'm talking about. You asked me what I recommended as a change, and then you're asking me to compare that to another technique which I don't recommend.

Q. What I'm asking you is, with regard to the medical literature that's evaluated, whether going bottom to top is better or worse than going top to bottom, the Ogah Cochrane review that you cited to in your review paper says that the retropubic bottom-to-top route used by TVT was more effective than the top-to-bottom, correct?

A. It does say this, but it's also quite minimal. I mean, a relative risk of 1.1 is practically the same. It may have statistical significance, but it's underwhelming.

So I answered your question.

Q. And the retropubic TVT

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bottom-to-top route also incurred significantly less voiding dysfunction, bladder perforations and tape erosions than the top-to-bottom route, correct?

A. Yeah, the tape erosions make sense, because you're doing it under direction vision. But the rest of the stuff is, again, relative risk, again, of 1.1.

I mean -- and these differences -- I mean, the differences, even though they may be statistically significant, are very unimpressive. I cited a 26-fold risk for perforation. They're citing a 1. -- so if you perforate, there's a 26-fold increase in the chances of perforation. And here they're saying if you use one versus another, there is a 10 percent -- excuse me, a 1 percent difference versus 26 percent.

So it's --

Q. The study you cited was not a randomized control trial, correct?

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A. No. It was a real-life study of who -- how could you -- you couldn't have a randomized control trial for that.

Q. That study you cited didn't assess complication rates for bottom-to-top midurethral slings versus top-to-bottom midurethral slings?

A. It did not.

Q. But what Ogah did was a comparative analysis of bottom-to-top and top-to-bottom, correct?

A. Yes. And I've already cited my objections to it.

Q. And they didn't demonstrate any benefit from going top to bottom, correct?

A. Correct.

Q. You said you would change the mesh design to reduce inflammation, erosion and scar contraction.

What would you change the design to?

A. I have -- that's for them to

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figure out.

Q. We just looked at your review paper that said that Amid Type I macroporous polypropylene mesh, and you cited the PROLENE®, is the preferred material --

MS. FITZPATRICK: Objection.

BY MR. SNELL:

Q. -- correct, in your review paper?

MS. FITZPATRICK: Objection.

THE WITNESS: I said that.

And it was also my opinion that the risk/benefit ratio using that is unacceptable. So that needs to be improved.

BY MR. SNELL:

Q. And you also concluded that using lighter weight, larger pore, smaller diameter pores and meshes doesn't have enough data, thus precluding any meaningful conclusions, right?

MS. FITZPATRICK: Objection.

THE WITNESS: Again --

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MS. FITZPATRICK: -- mischaracterization.
THE WITNESS: -- that's what I just said. Yes, they need to do better.
BY MR. SNELL:
Q. Are you aware of a synthetic midurethral sling, let's start with retropubic, that's available that has a lower rate of mesh exposure than the TVT retropubic?
MS. FITZPATRICK: Objection.
THE WITNESS: Unfortunately, I just didn't look at the literature comparing TVTs to other products. They are all -- they all have too high a complication rate.
And whether one is better than the other, it's still too high a complication rate in my judgment.
BY MR. SNELL:
Q. In the Cochrane review that

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you cited, they found that monofilament tapes, like TVT, correct, had significantly higher -- strike that.
In the Cochrane review you cited, they found that monofilament tapes -- and TVT is a monofilament tape, correct?
A. Correct.
Q. -- had significantly higher objective cure rates compared to multifilament tapes, correct?
A. That's been well documented, yes.
Excuse me, cure rates, you said?
Q. Yes.
A. If that's what it says, fine, I'm okay with that.
Q. And, also, the monofilament tapes, like TVT, had fewer tape erosions, correct?
A. Yes.
Q. There was a 1.3 percent with the monofilament tapes versus 6 percent

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with the multifilament tapes, correct?
A. Yes.
Q. And that's actually consistent with what you wrote on Page 11 that we were looking at earlier, where the Type II, III, IV meshes had a much higher incidence of erosion compared to Type I meshes, right?
A. Yes.
Q. Are you aware of any synthetic midurethral sling mesh on the market that has a lower rate of scar contraction than the TVT?
A. As I said, I didn't do a -- I didn't compare, in my evaluation, the TVT to others because I think the complication rate is high enough for all of them that the differences are -- aside from the Types II, III and IV, I don't think that the differences are enough of a difference to make a difference.
Q. So you wouldn't be aware of any synthetic mesh for stress incontinence that's on the market that

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has a lower rate of inflammation than the TVT mesh, correct?
A. I mean, quite honestly, even if there was, the methodology is -- I mean, I reviewed all the stuff. The methodology is not adequate to make those conclusions, in my judgment.
Q. That's fine.
MR. SNELL: Let's take a break. Let's go ahead and eat.
- - -
(Whereupon, a luncheon recess was taken.)
- - -
(Whereupon, Exhibit Blaivas-6, Curriculum Vitae of J. Blaivas, M..D., was marked for identification.)
- - -
BY MR. SNELL:
Q. Doctor, we're back from our lunch break. And during the break I marked as Exhibit 6 your C.V.
Is that a current copy of

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your C.V.?
A. I mean, it's fairly current. I mean, I have not seen -- this is the latest one I've seen.
I notice it doesn't have the last couple of articles. It doesn't have the mesh view article in it.
- - -
(Whereupon, Exhibit Blaivas-7, Blaivas Billing Report, was marked for identification.)
- - -
BY MR. SNELL:
Q. I marked as Exhibit 7 a document.
Can you tell us what that is?
A. Yes, that's my -- that's my billing report for this case.
Q. And it shows $22,500, correct?
A. Yes.
Q. And have you done any work after September 16th, 2015, up until

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before this morning when you showed up?
A. No.
Q. In your report on Page 10, you say that, The Gynecare TVT normally passes dangerously close to vital structures. The anatomic and positional variations render trocar passage more hazardous than theoretical considerations would suggest.
And you cite to a paper by Bhoyrul -- I'm terrible with pronouncing that.
MS. FITZPATRICK: Burt, have you -- is there a copy of this that's marked for the record, the expert report?
MR. SNELL: No.
MS. FITZPATRICK: Do we have one? Do you have an extra one?
MR. SNELL: I'm sure we have some over here, actually.
- - -
(Whereupon, Exhibit Blaivas-8, Bhoyrul Article, was

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marked for identification.)
- - -
BY MR. SNELL:
Q. Are you ready, Doctor?
A. I just need one second. Maybe off the record for one second, and then I'm going to turn this off.
- - -
(Whereupon, a discussion off the record occurred.)
- - -
BY MR. SNELL:
Q. So this is a study you cited about the -- pertaining to the TVT trocar and its risk of hitting structures.
As I read this study, Doctor, by Bhoyrul, and I don't know if that's how you pronounce it, it's B-H-O-Y-R-U-L, this study doesn't seem to be about TVT to me.
Does this study pertain to TVT?
A. No. It pertains to whether or not a trocar's design protects against

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injuries.
Q. Well, these are trocar injuries from laparoscopic surgery, right?
A. Yes.
Q. In laparoscopic surgery, you're actually taking the trocars and putting them into the abdomen, right?
A. Yes.
Q. Do you do any laparoscopic procedures using trocars?
A. I don't, no.
Q. You are aware that some doctors, most likely gynecologists, use laparoscopic Burch procedures as a potential option to treat stress incontinence?
A. I am.
Q. And is trocar injury a risk with doing the laparoscopic Burch?
A. Of course.
Q. There's a risk of injury with the trocar itself during a laparoscopic Burch, correct?

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A. Yes.
Q. And there's also a risk of doing the insufflation with a Veress needle during a laparoscopic procedure like the Burch, correct?
A. Yes.
Q. Have you ever done a laparoscopic procedure in your career? For stress incontinence, let's make it specific.
A. No.
Q. Do you know what the rates are of trocar injury following laparoscopic Burch?
A. I do not.
MR. SNELL: I'm going to mark another paper, Reynolds.
- - -
(Whereupon, Exhibit Blaivas-9, Reynolds Article, was marked for identification.)
- - -
BY MR. SNELL:
Q. Before we get into that

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article, Doctor -- actually, I want to follow up on what we were just discussing.
When you do your autologous fascial sling, is there any point during your procedure where you do not have direct visualization during the passage of any surgical instrument?
A. Yes. There's a -- yes, there is.
Q. When does that occur?
A. After you've dissected past to about the level of the bladder neck and then when you perforate -- once you've gotten into the retropubic space, you no longer have direct visualization.
And then, of course, there's no direct visualization for about maybe 2 centimeters between the rectus fascia and your finger in the retropubic space.
Q. When you harvest fascia lata and you use a tool like a fascia stripper, is that done blindly for some part of that procedure as well?

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A. I've never done that; but, yes, it's done blindly.
Well, no, it's not entirely blindly, no, I -- you -- part of it is blinded and part of it is not.
Q. Is it common, in stress incontinence surgeries, to have a portion of the procedure that is performed blind?
A. Those small parts I just said, yes.
Q. You have seen literature that reports bladder perforations during the Burch colposuspension, correct?
A. During the Burch?
Q. Yes.
A. Yeah, I don't have independent recollection that -- it's not something that I researched.
Q. But you are aware that bladder perforation does occur with the Burch colposuspension?
A. Rarely, yes.
Q. How would you define "rare"?
A. You know, I have -- I am

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going to retract that.
I have not looked at the literature about that particular problem, because it's of little consequence; bladder perforations are of little consequence unless you're using a synthetic.
MR. SNELL: Let's mark this.
- - -
(Whereupon, Exhibit Blaivas-10, Excerpt of Stress Incontinence Guideline, was marked for identification.)
- - -
BY MR. SNELL:
Q. Doctor, I've handed you Exhibit Number 10. And this is from the Stress Incontinence Guideline that you were a member of formulating for AUA.
You recognize this?
A. I do.
Q. This, particularly, is from the very large document available in the AUA's website regarding complications

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from the stress incontinence guidelines.
A. Yes.
Q. And if we go and -- let's go to Appendix A16, okay?
A. Yes.
Q. And you know why I'm going to A16, right?
A. Complications without prolapse, yes.
Q. So we're not having an interference with concomitant injuries due to a prolapse surgery, correct?
A. Yes.
Q. And that's why you broke it out of the data showing injuries with prolapse and injuries without prolapse, right?
A. Yes.
Q. And Appendix A16, complication rates, no prolapse, you all reported a 6 percent bladder injury rate following the Burch suspension, correct?
A. Yes.
Q. So isn't it correct, Doctor,

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that even with direct visualization during a Burch colposuspension, there can be injury to the bladder?
A. Yes. But as I said, the consequences of the injury are negligible when there's no synthetic involved.
Q. When a TVT sling is placed, let's go to -- you have to turn over a couple of pages to, Slings synthetic at the midline.
I'm sorry, let me rephrase that. Three pages back from where we were just looking.
So, Doctor, still Appendix A16, Slings. The middle column being, Synthetic at mid urethra?
A. Yes.
MS. FITZPATRICK: Wait a minute.
BY MR. SNELL:
Q. And that would be TVT, correct?
A. Yes.
Q. And there the rate of

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bladder injury was also reported at 6 percent, correct?
A. Yes.
Q. So that was comparable to what we saw with the Burch colposuspension, correct?
A. With the caveat that the consequences are different, yes.
And, also, for what it's worth, this is a much lower -- this is an older study and it's a much lower rate than -- it's a lower rate than subsequent studies.
Q. Well, what this study -- actually, this isn't a single study, this is an amalgamation of numerous studies, because you see the denominator for the midurethral slings was 1,925, right?
A. Yes.
Q. And you've read literature that shows that, in many cases, if there is a bladder perforation during a procedure in the TVT and it's recognized via cystoscopy, that the trocar can be

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withdrawn and then re-passed without complication to the patient?
A. I'm sorry, what was the question?
Q. How about this: You are aware that if a trocar from a TVT passage goes into the bladder and is recognized intraoperatively with the cystoscopy, that it can be withdrawn, repositioned, and many women do not have long-term complications or sequelae from that bladder perforation?
A. The only study that I'm aware of that addresses that issue is the one I cited before by Osborn, which shows a 26-fold increase in the likelihood of bladder -- of subsequent erosion.
So I'm not aware of any literature with data saying that -- I mean, with the -- yeah, I made my point.
Q. Just so we're on the same page and I understand.
You have not done any searches of the literature where you have

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found studies that reported on a certain percent of women who had a bladder perforation with the TVT, what percent of those did not have long-term complications or sequelae from that perforation?

A. I am not aware of a single study that addresses that question in a meaningful way, let's put it that way, in a way that -- whose methodology would support those conclusions.

Q. For the synthetic midurethral slings, you all assessed the rate of pain was 1 percent, correct?

A. Based -- where are you now?

Q. In the same table we were looking at.

A. Yeah.

Q. Suggested complications, correct?

A. That was two studies, and there was -- I'm quite sure there was -- there was insufficient methodologies to come to those conclusions.

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We did not comment on the quality of the methodology, just the reports themselves.

Q. And then below that, there's sexual dysfunction.

And that rate was zero percent with the synthetic midurethral sling, correct?

A. Yeah. If you believe that one, I'll sell you a bridge. But, yes.

Q. And, actually, Doctor, on that point, if you look down below there, you all didn't denote with any type of symbol that that data were not reliable, did you?

A. No, I don't see that we did.

Q. In fact, in the legend, there is a symbol where you could have designated that, where it says, Although this estimate is based on published data, the panel believes the estimates are not consistent with their experience.

No one elected to put that symbol next to pain or sexual dysfunction

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for the midurethral sling, correct?

A. That is correct. But I think that at the very -- to be kind, it was an oversight.

There is no way that the group that I was involved with would say that the -- that there is zero and 1 percent chance of sexual dysfunction and/or pain after a midurethral sling.

That's inconsistent -- even though that's what the paper says, that is inconsistent with any data or anything I've ever been involved with, with this group.

Q. If you go back to the Burch -- so that's what you're saying now.

You've never published that, correct, that there is --

MS. FITZPATRICK: Objection.

BY MR. SNELL:

Q. Strike that.

You've never published that these data in the AUA guidelines are now

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unreliable, correct?

MS. FITZPATRICK: Objection. Misstates the testimony.

THE WITNESS: The panel -- the guideline document itself said that the quality of the studies was -- I forget the exact wording, either poor or -- said that the quality of the studies was not good, that it was -- and being part of the discussions, we lamented the fact that there were so few studies to make -- to come to any reasonable conclusions.

And we were forced, by the -- we were forced, by the dictates of the organizing body that put this together, they told us that we needed to rely on the data that was -- that the paper -- that -- the published data to come to our conclusions.

And that's what the group did. I don't think anybody -- I'm

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confident that nobody on that committee would say that there is a zero incidence of sexual dysfunction and a 1 percent incidence of pain after midurethral sling.

Every single study in the literature that I ever reviewed that looked at any -- either sexual -- either dyspareunia or pain has an incidence higher than 1 percent. So I don't know how this happened -- I don't know how this occurred.

BY MR. SNELL:

Q. Are you still a member of the AUA?

A. I am.

Q. Why?

A. Why am I a member?

Q. Why are you still a member of the AUA?

MS. FITZPATRICK: Objection.

THE WITNESS: Because I

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think it's an important organization and it provides valuable services to the public and its membership.

BY MR. SNELL:

Q. Well, if you look at the page before that, you'll see that you all did indicate -- what do you call that an ampersand?

MR. ROSENBLATT: Asterisk.

MR. SNELL: No, like a double S.

THE WITNESS: I know what you mean.

BY MR. SNELL:

Q. Do you see the page before that, Doctor, you all indicated, in two different places with that ampersand, that the data estimated were not consistent with their experience.

Do you see that? For bladder injury as well as vaginal erosion extrusion for synthetic slings at the bladder neck with bone anchors, correct?

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A. I see that.

Q. And if we turn back two pages, we were looking at the Burch colposuspension, the rate of pain you all reported in the stress incontinence guidelines for the Burch was 6 percent, correct?

A. Which page are you on?

Q. Back where we were, Burch colposuspensions, Table 16.

A. And where?

Q. It's at the bottom.

A. Okay.

Q. And the way these tables read is, there's different surgical methods that have their own column, correct?

A. Yes.

Q. And for the Burch colposuspension, you all reported that the rate of pain was 6 percent, correct?

A. Yes.

Q. And that was higher than what you reported for the midurethral

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sling, correct?

A. Yes.

Q. You reported that sexual dysfunction was 3 percent with the Burch colposuspension?

A. Yes.

Q. And that was less than what you reported for the midurethral sling, correct?

A. Yes.

Q. Do you believe these numbers for pain and sexual dysfunction with the Burch are now somehow inaccurate?

A. I don't know. I don't have an opinion about that. It's not something I reviewed.

Q. Where did you all -- I was trying to find it.

Where did you report, in these tables, ureteral injury?

A. I don't know if they're there.

Q. I see it. So ureteral injury, let's look right above where we

Page 166

were at for the Burch for pain and sexual dysfunction.
You all reported a 1 percent rate of ureteral injury for the Burch colposuspension?
A. Yes.
Q. How does one injure the ureter during -- strike that.
Is that the urethra or the ureter?
A. Ureter.
Q. How does one damage the ureter during a Burch colposuspension when it's an open visualized procedure?
A. Because you don't expose it and it's very close by. It doesn't surprise me at all.
Q. Really?
A. Yes.
Q. When we were -- let me put this down.
Going back to your paper, your review paper -- what did we mark that as, Doctor?

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A. 4.
Q. 4. Okay.
In your paper, Exhibit Number 4 -- strike that.
In Exhibit Number 4, your review paper from this year, look at the references towards the back on Page 28.
A. Yes.
Q. For example, you cited to Dr. Klinge at Number 342 regarding the reaction of meshes used in hernia repair.
A. Yes.
Q. Are you aware of Dr. Klinge's publications concerning TVT mesh?
A. You know, he has -- I don't -- I don't know if he has -- I know he did mostly abdominal and more basic science stuff. I mean, he has an enormous C.V. on this stuff. I just don't know if he did or not, TVT.
MR. SNELL: Let's mark this as an exhibit.
- - -

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(Whereupon, Exhibit Blaivas-11, Excerpt from Hernia Book, was marked for identification.)
- - -
BY MR. SNELL:
Q. So Exhibit 11 is an excerpt from a hernia book. And you see, if we turn to the page, Chapter 56 is about implants for stress incontinence and prolapse.
A. Yes.
Q. Have you ever seen this document?
A. I've seen so many of his that I don't know if I've seen this or not. I've not seen it in color, most of them -- I'd have to check my reference list.
I mean, he has, I think, hundreds of documents with similar titles.
Q. You're aware that the vast, vast majority of his publications concern

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hernia mesh?
A. Yes.
Q. This is one where he writes about the TVT?
A. Okay.
Q. You see under meshes and stress urinary incontinence?
A. Yes.
Q. All right. Dr. Klinge writes, At present, the gold standard in SUI surgery is the suburethral sling using either the tension-free vaginal tape, TVT -- and that's the device we're talking about here today, right?
A. Yes.
Q. -- or the transobturator tape. The two procedures do not seem to differ in efficacy, with TOT being advantageous because of a lower rate of bladder injuries.
Do you see that?
A. I do.
Q. Were you aware that Dr. Klinge had referred to TVT as the gold

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standard --
A. I don't believe --
Q. -- for the treatment stress incontinent surgery?
A. I'd be surprised if he has any expertise in stress incontinence surgery, and he's probably just quoting something he read.
Q. So you disagree with Dr. Klinge, who says that TVT is the gold standard in SUI surgery?
MS. FITZPATRICK: Objection. Misstates the testimony.
THE WITNESS: I think that's different than what you asked me about.
You said if -- whether or not I thought he thought that it was.
I quite agree that he wrote this down, but I -- but that -- I don't believe that this is -- I think this is background material that he would have gotten from

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someplace else.
I don't think he has any -- and I apologize to him if I'm wrong, but I don't think he has any standing to decide for himself what's a gold standard or not.
I don't disagree -- so that's all I'm saying.
BY MR. SNELL:
Q. Well, you and Dr. Klinge agree, if you look at the next paragraph, right, because we saw this in your review paper, The initial concern that if mesh is used might lead to high rates of erosion did not hold true when macroporous polypropylene was used.
That's consistent with what we went over in your review paper, right?
MS. FITZPATRICK: Objection. Misstates the testimony.
THE WITNESS: Well, I mean, I prefer not to use the words "high" or "low." It says high rates, he gave a number. And I

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already cited my objection about long-term trials with respect to complication rates.
And 1.7 percent is keep -- in the same ballpark that we quoted, the 1.7 and 3.1 percent respectively. So we agree on an approximate rate of erosion, that it's in the single digit percents. There's no disagreement about that.
BY MR. SNELL:
Q. You agree with Dr. Klinge that the macroporous monofilament Type I polypropylene mesh has a lower rate of mesh exposure than the Amid Type III meshes, correct?
A. They all have an unacceptable high erosion rate, and the Type Is are better than the Type IIs, IIIs and IVs.
Q. You see down below where he cites to study on incontinence by Meshia, where they compared Amid Type III mesh

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that had a 9 percent exposure rate to zero percent in that study for the classic TVT Type I?
A. I do.
Q. And that's consistent with what you wrote in your review paper, correct?
MS. FITZPATRICK: Objection.
THE WITNESS: Well, zero percent is the lower end of what we wrote. But, yes.
BY MR. SNELL:
Q. Do you disagree with Dr. Klinge's statement that the gold standard -- strike that.
Do you disagree with Dr. Klinge that the gold standard in SUI surgery is the suburethral sling, either the TVT -- particularly the TVT?
A. No, that's -- I don't believe it's the gold standard. I think it's a gold standard, along with the autologous rectus fascial sling.
Q. Having read this, does this

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refresh your recollection whether you were ever given this paper?
A. It doesn't, because, I mean, this is such a generic statement, that I -- I may well have read it. And -- it's a book chapter, it's not a peer review, and it's just citing other literature and very selected other literature.
Q. I got the Serati paper we were talking about earlier. I wanted you to have an opportunity to evaluate that.
- - -
(Whereupon, Exhibit Blaivas-12, Serati 10-Year TVT Paper, was marked for identification.)
- - -
BY MR. SNELL:
Q. So, Doctor, we marked the Serati 10-year TVT paper as Exhibit 12. And this is one of the papers that didn't show up in your review?

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A. Correct.
THE WITNESS: I'm sorry?
MS. FITZPATRICK: Hold on. When you say "review," I'm going to object to that question when you use the term "review."
BY MR. SNELL:
Q. Doctor, this is a review paper that you published, Exhibit 4, correct?
A. It is on my reliance list, but it is not on -- in that paper.
Q. And this is a paper where they included 63 women, and after ten years, there was an 8 percent loss to follow up?
A. Correct.
Q. Have you assessed the literature as -- to see what is the average or expected rate of loss to follow up in a stress urinary incontinence surgery cohort at ten years?
A. I haven't studied it, but I certainly have a sense of it.

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Q. You've already told me that for the pubovaginal autologous sling, there are no ten-year studies, correct, that you're aware of?
A. Not that I'm aware of.
Q. So you have no idea what loss to follow up would be with that procedure ten years or more, correct?
MS. FITZPATRICK: Objection.
THE WITNESS: No. I -- well, you can't have a -- if there was a ten-year follow-up, I do have an idea of what the loss to follow up would be.
But -- for what it's worth. I mean, in answer to your question, if there was one, I do have a sense of what it would be.
BY MR. SNELL:
Q. All right. So tell me -- go ahead and tell me what you think it would be and what's the basis for that?
A. Just from looking at lots of other studies. It probably -- if it's a

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contemporaneous ten-year study, we probably would have a loss to follow up in the -- I would say, in the 15 to 30 or more percent.
Q. That's because over ten years, that's a long period of time, correct?
A. Yes.
Q. People can move, correct?
A. Correct.
Q. Certainly, patients can die, correct?
A. Yep.
Q. There are many reasons for loss to follow up, correct?
A. Yes.
Q. But 8 percent loss to follow up in a ten-year study regarding TVT is actually pretty good follow up, you would agree with that?
A. Yes, I would.
Q. And what they found was that the ten-year subjective/objective in urodynamic dynamic cure rates were all

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around 90 to 93 percent correct?
A. They did. But I should point out that it was a very, very highly select group of patients. These were the best possible candidates; 91 of 141 patients were excluded because of pelvic organ prolapse.
But they defined pelvic organ prolapse for this study in a way that would include many normal patients based on what we now know is normal for prolapse.
So this is -- I think this is a very good but very -- but very biased study in its selection of who to follow up. So to exclude well more than half of the patients because they had a degree of prolapse which other studies -- which we now consider to be normal means that you're selecting the very best of the best of the best candidates, and you're saying the patients that are most likely to succeed do, in fact, have a high success rate.

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Having said that, because I don't want to -- this to come across wrong, I think this is a very well done study, with that caveat.
Q. And we can agree that there are reasons why you would want to exclude women with prolapse when -- particularly when you're doing a ten-year study to evaluate a device, because you know that prolapse, over time, can lead to urinary problems, defecatory problems and sexual problems; those are possibilities, correct?
A. Yes. But what I said is that many of the patients in the study that they excluded for prolapse did not have prolapse according to our current definition of prolapse.
Q. That's fine. According to the current definition.
But you -- when you do a study that was done probably 15 years ago, you base it upon the current state of knowledge and definitions at that

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time, right?
A. Well, the current state of knowledge is what we have now. And then we critically look at the paper.
I don't want to nitpick about this. I think this is a well done study, okay? But I do think that if you're talking about efficacy and complications, there's virtually nothing in here, zero, about complications, other than a rather high rate of de novo overactive bladder.
But the kind of complications that we were talking about in our review, this doesn't even assess them at all.
Q. Let's see if we can agree on something, because I think we do. And it pertained to my use of the word "current," okay?
When a study is done, at the time it's done, it's done according to then current thinking, state-of-the-art standards, correct?

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MS. FITZPATRICK: Objection.
THE WITNESS: Of course.
BY MR. SNELL:
Q. Not a re-definition of prolapse that occurs by Matt Barber and other people 12 years down the road, correct?
A. Correct.
Q. When studies are done, they are done contemporaneous with the art in the field of stress incontinence, correct?
MS. FITZPATRICK: Objection. Is there a particular study or are you asking him to -- whether all studies are necessarily --
MR. SNELL: You're doing a speaking objection.
MS. FITZPATRICK: The question is completely indecipherable. And you know you're trying to mislead here, Burt.
MR. SNELL: No, I'm not.

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MS. FITZPATRICK: Just tell him what you're looking for.
Are you asking him --
MR. SNELL: You're doing speaking objections. Stop doing speaking objections.
MS. FITZPATRICK: I don't care what you think, Burt. Come on, play fair.
MR. SNELL: I am playing fair.
MS. FITZPATRICK: No, you're not.
MR. SNELL: I think I'm very fair.
MS. FITZPATRICK: No, you're not.
MR. SNELL: I'm not misleading the doctor at all. You're wasting my time.
MS. FITZPATRICK: Objection. Don't answer the question, it's an indecipherable question. Ask a new question or move on.

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BY MR. SNELL:
Q. First of all, Doctor, you've done studies over a different decades of time, correct?
A. I have.
Q. And when you did a study, you did it contemporaneous with the state of the art and the knowledge in the field at the time you conducted the study, right?
A. I did.
Q. You didn't try to say, 12 years down the road something might change, so let me conduct my study according to some future standard, did you?
A. No.
Q. So you understood, when I was talking about what was state of the art, at a current time a study was done, correct?
MS. FITZPATRICK: Objection. He cannot -- objection.
THE WITNESS: I understand.

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But we're evaluating it today. We're not -- I mean, I already said, the assessment today has to take into consideration methodologic flaws. And we do that in every paper, no matter -- we look for the scientific integrity of the paper.
Based on what they knew then, this was a very well done paper. Based on what we know now, it's also a very well done paper, except for the conclusions, I think, are -- we have to be somewhat circumspect, because it's a highly selected group of patients.
The results stand for themselves in a highly select group of patients. That's all I'm saying.
BY MR. SNELL:
Q. If the pubovaginal sling was assessed under the same methodology at

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the same time period by the same surgeons, would you have the exact same outlook on the study?
A. Of course.
MS. FITZPATRICK: Objection.
BY MR. SNELL:
Q. You mentioned, you know, complications weren't assessed. But look at Page 942, Doctor. Right above the discussion section.
Do you see that?
A. Yes.
Q. It says, During the final visit, voiding difficulties were reported in two patients.
Did I read that correctly?
A. Yes.
Q. All right. And this is the point I want to follow up on.
This study actually does report on the need for tape release or resection, doesn't it?
A. Yes. But this is the problem, it's done -- it's a prompted --

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it's prompted. It's not -- the methodology doesn't include methods to determine whether or not any -- for example, whether or not -- whether -- I'm sorry, I'm getting a little tired -- whether or not a mesh revision was necessary; it just said of those patients that we followed, it wasn't.

The problem is, for all of these studies, is that in at least a third of the patients, at least a third of the patients, and I believe it's more like 50 to 75 percent of the patients, who do undergo mesh revisions, the implanting surgeon has no knowledge of that, the patient never goes back to the doctor.

So the loss to follow up becomes critically important, even the 8 percent, I think, is as good -- is as good a loss to follow up as you can see. But since we're only surmising, our data would suggest that the chances of having -- of requiring another operation

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are only -- are way less than 8 percent.

So in order to -- and since we know that the loss to follow up is more likely -- that a patient who has an operation is more likely to be lost to follow up, there simply isn't methodology in this study to answer the question whether, in fact, the patients lost to follow up did require further surgery, even the patients that died could have required further surgery.

And that's --

Q. There are always possibilities, correct?

A. There are always possibilities --

MS. FITZPATRICK: Objection.

THE WITNESS: -- but when you're making a claim that something didn't happen -- if you're making a claim that nobody required mesh revision and you know that the chances of requiring mesh revision are, say, 4 or 5

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percent, if you power a study to look at that, you'd have to include a much larger -- much, much larger number of patients and you'd have to figure out either what happened to the loss of follow up or you'd need a much larger, much, much larger study than 63 patients to answer that question.

You don't need that many patients to answer a question about efficacy.

BY MR. SNELL:

Q. Well, what they were able to report says, with the caveat, and they reported that there was 8 percent loss to follow up, No patient required tape release or section during the ten-year follow-up.

Correct?

A. That's what they reported, yes.

Q. And in the patients who came

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back and were able to be assessed, it says there was no de novo dyspareunia in those 58 patients, correct?

A. Correct.

Q. Are you aware of any Burch colposuspension studies that have ten years or more follow up that have a loss to follow up rate that's less than 10 percent?

MS. FITZPATRICK: Objection.

THE WITNESS: I actually am. I can't remember the name now, and I don't know if we reviewed it. There, actually, surprisingly, were two or three Scandinavian studies. I forget if they were Norway or -- I don't remember where. But they actually had 100 percent, they had no loss to follow up after ten years.

BY MR. SNELL:

Q. Is this with Burch or TVT?

A. Burch. You asked about Burch.

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Q. Yes.
A. Yes, this was Burch. I'm quite certain about that, because I was shocked to see it. But it was so long ago that I read it, I couldn't possibly tell you when.
Q. Considering that you included the five-year TVT-O study by Serati in that table but you didn't include this ten-year TVT study, as you sit here now, I know I asked you this earlier, but do you know why that was not captured?
MS. FITZPATRICK: Objection. Asked and answered.
THE WITNESS: I am going to find out. I don't know why.
BY MR. SNELL:
Q. This study is consistent with your review, in particular with regard to the rate of dyspareunia long-term with TVT, correct?
MS. FITZPATRICK: Objection.
THE WITNESS: A dyspareunia

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rate of zero? No. It's not -- we don't have -- not a zero dyspareunia rate. It's no dyspareunia.
BY MR. SNELL:
Q. Right. Maybe I messed the question up.
Actually, this study by Serati, the ten-year follow-up, is actually consistent with what you wrote in the AUA stress incontinence guidelines, correct, with regard to dyspareunia rates?
A. That's correct, yes. I thought you were referring to our Nature article.
Q. And this study by Serati, that you didn't include in the Nature article, is inconsistent with what you wrote in your review article, correct?
A. In what way?
Q. Because it reports zero dyspareunia and you say there's more, correct?

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A. Yes.
- - -
(Whereupon, Exhibit Blaivas-13, Heinonen Paper, was marked for identification.)
- - -
BY MR. SNELL:
Q. I have another one for you. I'm not going to go through all of the ones, but I'm going to give you a couple of them.
I've handed you Exhibit 13. This is a paper by Heinonen. This is a 10.5 year follow-up with Ethicon TVT.
Do you see that?
A. Let me just take a look.
Q. Sure. And I think we can be pretty brief about this one.
This is a long-term study on TVT, correct, Doctor?
A. Yes.
Q. This paper was not identified in that long-term study table either in your review, correct?

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A. That's correct.
Q. In this study, there was about 28 percent loss to follow up, correct? 138 of 191 patients were able to be evaluated?
A. If you did the math, that looks about right. Okay.
Q. They say 72 percent.
Do you see that?
A. I do.
Q. So that's within that range of what's to be expected at ten years, correct?
A. Yes.
Q. And these authors concluded that the TVT was effective and safe even after ten years, correct?
A. Yes. We've agreed that it's effective.
The safe, just give me a moment, I'm checking.
Okay.
Q. Do you know why you didn't cite to this paper either in your table

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of long-term TVT studies?
A. I do not.
Q. They reported three --
strike that.
They reported three
patients, 2.3 percent, had late-onset
adverse events, correct?
A. Where is that, please?
Q. It's in the very front.
A. Okay. I mean, I was looking
in the methods, and there's nothing in
the methods that I can see about
adverse -- about any mechanism to
follow-up for adverse events. So let me
just --
Q. Well, you see, if you look
under the methods, the fourth paragraph
above, when they brought these women back
in for this 10.5 year follow-up visit --
A. Where are you now?
Q. Right here. Right above
results. They did a gynecologic exam, a
stress test, they reviewed the hospital
records.

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And it says, This was done
to acquire information on later
acquired...adverse events after the TVT
operation.
Correct?
A. Yes, that would account for
some complications. It would not account
for the most impactful complication,
which is chronic pain. You wouldn't,
likely, go to the hospital for that.
But I accept the rest of it.
Q. Well, none of these patients
reported chronic pain when they were
assessed at 10.5 years, did they?
A. I didn't see -- I looked,
and I'll look again, but I don't see
anything in the methodology where they
were asked about that.
General quality of life and
the stuff that -- this was all -- so far
as I can see, was -- all of these were
questionnaires. I don't see anything
that wasn't a questionnaire.
And there are no

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questionnaires -- I know most of these
questionnaires, most of these
questionnaires would ask specifically
about dyspareunia or pelvic pain.
Q. Did you see that they did
gynecologic exams?
A. Yes, but that's not --
that's not a measure of pain.
Q. Well, during -- you do
gynecologic exams, correct?
A. Yes.
Q. And you know that when you
do a gynecologic exam, you can elicit a
painful response from the patient,
correct?
MS. FITZPATRICK: Objection.
THE WITNESS: Yes.
BY MR. SNELL:
Q. Do these authors, at 10.5
years, report that they elicited any type
of painful response from any patient
during their gynecologic exam?
A. I don't see any methodology
that would ask for that. I mean, the way

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all these studies are done, eventually
this stuff becomes a table, and the table
is going to be a score and there's going
to be a score for each of the symptoms.
And unless there's a score for pain or a
score for dyspareunia, even if the
patient had it and even if they told
someone, there isn't a mechanism that I
can see in the methods to discover that.
Q. So the different
questionnaires, it's your statement that
none of those questionnaires would have
assessed pain or the impact of
incontinence on sexual function?
A. Even if -- I mean --
Q. It's a yes-or-no question.
A. What's that?
MS. FITZPATRICK: Objection.
Objection. You can answer it any
way you need to, to fully,
completely and truthfully answer
the question.
THE WITNESS: Please
rephrase the question. Not

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rephrase, just restate it.
BY MR. SNELL:
Q. Do any of the questionnaires that they used assess sexual function in any manner?
MS. FITZPATRICK: Objection.
THE WITNESS: None of the ones that I recognize do. I mean, it's -- none of the ones that I recognize do, is the answer to the question.
BY MR. SNELL:
Q. This paper was published in the International Journal of Urology.
Are you familiar with that journal?
A. Yeah. Yes, I am.
Q. Is that a good journal?
MS. FITZPATRICK: Objection.
THE WITNESS: I think it's -- yeah, I think it's an adequate journal.
BY MR. SNELL:
Q. Is this a good study or a

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poor study? How would you characterize this study that wasn't included in the table of your review?
A. I would characterize this as a very good study. Both of these are very good studies.
Q. Do you have any idea why this wasn't included?
A. I do not.
Q. Are you going to attempt to try to figure out why these ten-plus year TVT studies were left out of the table and which other ones may have been left out, too?
MS. FITZPATRICK: Objection.
THE WITNESS: I've already started doing that.
But, in context, this review is not about efficacy, it's about complications. So there wouldn't -- this -- neither of these papers, as far as I'm concerned, adds very much to our understanding of the incidence and

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consequence of complications.
That was the purpose of -- that was the purpose of the review.
- - -
(Whereupon, Exhibit Blaivas-14, 2014 Laurikainen Article, European Association of Urology, was marked for identification.)
- - -
BY MR. SNELL:
Q. Doctor, I'm handing you a five-year randomized control trial by Laurikainen, published in the European Association of Urology, January 2014.
Do you see that?
A. I do.
Q. This is another study that didn't show up in that table in your review article, correct?
A. Yeah, my -- I'm pretty sure that this one is after our -- even though it says 2014, I'm pretty sure this was

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after our review dates.
And this one I have seen, though. This one, I do remember seeing this one before.
Q. It's interesting that you say that, because, Doctor, earlier we looked at the review criteria, and it states that the systematic review was done in August 2014, which is, you know, eight months after this was published, correct?
A. I was looking, I don't see the actual publication.
Q. It says on the left, Published online, January 30, 2014.
A. Then I don't have an explanation. I don't know what the exact date of our cutoff was.
Q. But the search was done, actually, in August 2014, which is months after this was published?
A. Okay.
Q. We can agree to that, correct?

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A. I don't -- let me see.
Q. I wouldn't --
A. Let me just take a look.
Yes.
Q. And this randomized trial reported on efficacy and complications, correct?
A. Yes, it did report on it.
Q. And if you'd go to the very back, last page, Page 5.
A. If I might, I just -- I'd like to just read the methods again.
MR. SNELL: Why don't we go off the record, then, because I don't want this counting against my time.
- - -
(Whereupon, a discussion off the record occurred.)
- - -
BY MR. SNELL:
Q. So this study only has a 5 percent loss to follow up, correct?
A. Yes.

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Q. And that's pretty good?
A. That's excellent.
Q. European Urology, is that a -- considered a good or an adequate journal in your field?
A. Yes.
Q. And this study, you saw in the methods that they did look for tape erosion, extrusion?
A. Yes.
Q. And if you'd go to the fourth page, right above the discussion section.
A. I need just one moment here.
Okay.
Q. Typical mini-stress incontinence surgery papers, they looked at and reported on efficacy, and then they discussed complications, correct?
A. Yes.
Q. And the efficacy for the TVT group in particular --
A. Yes.
Q. -- was good, correct?

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A. Where is that?
Q. Objective cure rate was 84.7 --
A. Where are you?
Q. I'm actually looking at the -- in the results.
A. I'm with you.
Q. Objective cure rate at 5 years in the TVT group was 84.7 percent and subjective treatment satisfaction was 94.2 percent in the TVT group, correct?
A. Yes.
Q. And that shows the utility of TVT treating stress incontinence, correct?
A. Yes.
Q. And if you look at the section where we were talking earlier, right above discussion, on the fourth page, it says, No woman had any sign of tissue reaction, erosion or tape protrusion at their five-year follow-up.
Correct?
A. Yes.

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Q. And it says, During the course of the study, two women experienced tape problems, both were in the TVT-O arm, transobturator arm.
Correct?
A. Yes.
Q. Do you have any idea why this five-year randomized control trial on TVT was not included in your review?
A. I think you already asked me, and I answered it. It's painful for me to answer it again. I don't know.
Q. You would agree this is a good study?
MS. FITZPATRICK: Objection.
THE WITNESS: I think it's a good study for everything except, once again, complications. There's no measure or methodology that asks about pain or -- pain or dyspareunia. There's nothing about how many were sexually active, whether before and after, and there's nothing -- and there's

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no -- nothing about pain and nothing about dyspareunia.
BY MR. SNELL:
Q. Well, they did report on tissue reaction, erosion and tape protrusion, correct?
A. They did.
Q. And in the methods, they talk about how tape extrusion and erosion was explored through clinical exam, including speculum exam in the --
A. I agree with that. I'm okay with that statement.
Q. So this is a study -- strike that.
So this study reliably reports no tissue reaction, erosion or tape protrusion in the TVT patients for those complications at five years?
MS. FITZPATRICK: Objection. Misstates earlier testimony.
THE WITNESS: Correct.
BY MR. SNELL:
Q. Your criticism is that, in

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your view, this study did not look for the pain and dyspareunia endpoints?
MS. FITZPATRICK: Objection.
THE WITNESS: Yes. And there also was a -- I thought there was something about -- there was something about overactive -- de novo overactive bladder. I can't find it right now. But they did report on that, yes.
The main critique is that there is no methodology that looks at what I consider to be the most disabling aspect of the complications, which is pain and dyspareunia. And the -- all these papers you're citing show the efficacy that we've already agreed to.
BY MR. SNELL:
Q. If pain reported -- strike that.
If patients reported pain or dyspareunia in this study to

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investigators, would you expect it to be reflected in the study?
A. I would expect probably yes. But the more important thing is that many patients, and this has been our experience and this is in the published literature in the Hansen Changed Woman article, for example, many patients with pain and dyspareunia do not report it. They think it's part of the problem or people don't care or they're embarrassed.
So some of the most disabling -- some of the most disabling aspects of this may never get into an otherwise very good study.
I'm not really critical of any other aspect of this study. I think it is well done, and I accept the -- in this particular paper, the low complication rate for erosions and the kinds of things that are more common in some of the other studies.
So my only critique for this one is that there's no methodology for

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those few things.
Q. The dyspareunia is common in the background of women who are of the age who usually undergo stress incontinence surgery, correct?
MS. FITZPATRICK: Objection.
THE WITNESS: Well, it -- the average age is pretty -- is actually pretty low. It's in the early 50s.
And I'm not -- you know, I think dyspareunia is much more common as people get older. So I'm not sure what the actual rate is at that level.
BY MR. SNELL:
Q. When you say some women who have pain are not going to report it, is that unique to stress incontinence patients or is that an observation based on data pertaining to just women in general?
A. Well, the literature that I'm referring to is specifically the

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stress incontinence patients who have undergone mesh surgery. But -- and I have not looked at the other literature.

But, no -- but I do think it's common, period. I think that pain and sexual dysfunction, even when it's after these kind of surgeries, particularly a lot of the women who I've seen, have just thought it's kind of part of the process, you know, that they had surgery and it hurts and there's nothing you can do about it.

Q. I think you mentioned the urge --

A. Overactive bladder symptoms, yeah.

Q. Right. They did report on that in this study.

You see --

A. Yeah, I agree.

Q. -- at five years, de novo urgency incontinence was experienced in 28 percent of the women at five-year follow-up, correct?

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A. Yes.

Q. 2.8 percent de novo urge incontinence --

A. 2 what?

Q. 2.8 percent de novo urge incontinence at five years, how does that --

A. Where is that?

Q. Right there where you were looking at. I think that's what you saw.

A. And what was your question?

Q. There was de novo urgency incontinence experienced by 2.8 percent of women at five-year follow-up, correct?

A. Yes.

Q. And how is that rate comparable to five-year follow-up women after Burch or autologous pubovaginal sling?

A. Well, I'm not that aware of the data from Burch, but it's one of the lowest rates I've seen. That's very good.

Q. Is it correct, Doctor, that

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over time, five years, ten years, in women who have baseline stress incontinence, a certain percent of them will develop urge incontinence?

A. Yes.

Q. Do you know -- and so that would be the background epidemiologic rate of progression of urge incontinence, correct?

A. Yes.

Q. Do you know what that rate is at five years or ten years in the literature, in general, for these patients?

A. Yeah, it gradually increases with age. I couldn't give you a specific number.

Q. If you look over to the next column, there were about 3 percent of women who had de novo urge incontinence develop, correct?

A. Yes.

Q. And that's a known risk with all incontinence surgeries, correct?

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A. Yes.

Q. If you look over on the right column, it reports that 84 percent of the women were cured who had preoperative urgency symptoms.

A. God bless, yes, these are very -- I mean, you're selecting one of the best outcomes in the literature. And I think the study is well done. This is a good study.

Q. So that's a benefit of TVT, and you know that from your review of the literature, that --

A. No -- go on, sorry.

Q. -- that even patients who have preexisting urgency symptoms or urge incontinence, some of them, after TVT, will have a reduction in their urge symptoms?

A. That's a generic statement for any -- for any of the sling operations. In fact, I believe we were one of the first people to report nearly a 90 percent improvement, after

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autologous sling, in people with overactive bladder symptoms. So this supports that.

But, again, when you -- you made the general statement about TVT, and this is one of the best results in the TVT that I'm aware of in the retropubic sling literature. So this is hardly representative of all the retropubics that are done.

Q. Well, what I'm saying, Doctor, and I think we can agree on it, is that it is a benefit, a utility to TVT that a certain percentage of women will have improvement in their preexisting urgency symptoms, correct?

A. Well, not specific to TVT. It's -- for any -- it's just as good for autologous sling. It's not specific -- I mean, the way you're phrasing the question, it sounds like you're saying it's specific to TVT, and I don't believe that.

TVT is one of the operations

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that can achieve these results.

Q. With the Burch colposuspension, do you believe it improves preexisting urgency as much as TVT does?

A. Honestly, I just don't have an opinion about that. I'd have to research that.

Q. Do you believe that TVT and the autologous pubovaginal sling both improve preexisting urgency to the same degree?

A. I think in the hands of good surgeons -- in the -- with properly done procedures, I think the answer -- properly done, the answer is probably yes -- is yes.

Q. And so now we've gone through this study.

Any idea how it didn't come to make it into your five-year long-term table?

A. This is the third time you asked me the same question. I still

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don't know the answer, no.

Q. The incidence of urgency increases with age, fair?

MS. FITZPATRICK: Objection.

THE WITNESS: Yes.

BY MR. SNELL:

Q. My colleague over here thinks that I'm not asking you questions.

- - -

(Whereupon, a discussion off the record occurred.)

- - -

(Whereupon, Exhibit Blaivas-15, Blaivas Pubovaginal Sling Paper, was marked for identification.)

- - -

BY MR. SNELL:

Q. So, Doctor, this is one of your papers on the pubovaginal sling?

A. Yes.

Q. Earlier in the deposition, you testified that in your series that you had reported on, some of the ladies

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had more than ten-year follow-up, correct?

A. In my -- I don't believe I said it in -- I don't know if I said it in the -- my published literature, but I have many patients that -- I don't know. I mean, I'd have to look.

Q. My question was this: This is a paper I found where you reported on some patients and the follow-up range from was one to eight years, but the mean follow-up was 3.5 years, correct?

A. Yes.

Q. Have you published on your experience with the autologous pubovaginal sling with a mean follow-up in your cohort of patients of five years or greater?

A. I don't think so.

Q. I hadn't seen it either, but I didn't know if I had missed it.

- - -

(Whereupon, Exhibit Blaivas-16, 2007 International

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Journal of Urology Paper, was marked for identification.)

- - -

BY MR. SNELL:

Q. Doctor, this is another paper out of the International Journal of Urology, 2007, concerning pubovaginal sling procedures, do you see that? With autologous rectus fascia, correct?

A. I do, yes.

Q. And that's the same type of procedure you do?

A. I'll let you know in a minute.

No, this is not -- I mean, this is not a -- this is one of those that didn't make an effort to -- they say they -- there are a number of differences between the methodology that they describe and what I do.

Q. Is it correct that surgeons can have their own individual variations in the way they carry out an autologous pubovaginal sling procedure?

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A. Of course.

Q. And that's just understood and recognized and accepted in the art?

A. It's recognized, yeah. I suppose accepted, yes.

Q. In this study, they report on 10 percent, three of the patients developed persistent urinary retention or severe voiding difficulty after surgery and they underwent urethrolysis, correct?

A. Correct. And the methodology -- that's why I immediately picked up on their method, I would predict that from the way they did the surgery.

This is -- to me, even though this is reported in 2007, in my judgment, it was -- the technique is one that -- the concept is one we abandoned in the mid 1980s.

Q. All these surgeries look like they were carried out between 1998 and 2005 in this cohort of women?

A. Yes.

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Q. And urethrolysis is where you cut the sling?

A. No. Well, actually, let me see what they -- again, unfortunately, people use different -- the same words to mean different things. So let me see if they say.

No, they don't define -- they don't define any of their -- the methods for this, so I can't -- I don't know what they meant by urethrolysis.

Cutting the sling, I would have used the term sling incision. And it doesn't make sense to do urethrolysis if the sling is too tight. You cut or excise the sling. I don't know what they meant.

Q. If a TVT sling is too tight, do you cut or excise the sling?

A. Me personally or --

Q. In general.

A. There is no in general. I personally excise the portion underneath the urethra. Many of my colleagues will

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just incise it.

Q. You've seen literature reporting that after you incise a TVT in a woman who has retention, that she can remain continent?

A. That she what?

Q. Can remain continent?

A. Yes.

Q. Have you experienced that in cases that you've done yourself, where you've gone in and removed the suburethral portion of a TVT, that some patients remained continent?

A. I would say in the ones I've done, most have.

Q. And in this study, it reports 28 percent of the patients with the autologous sling needed prolonged intermittent self-catheterization.

My question to you is, how does that rate compare with your understanding as to the overall literature?

A. 28 is very high.

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Q. When surgeons talk about intermittent self-catheterization, what time period are they talking about?
A. Either -- I mean, I would say a maximum of three months. But, I mean, most people -- even -- most people, if they are keeping that data, would include even if it's a matter of days or weeks or something.
I mean, some of the papers simply state how long it was for.
Q. When you do your autologous slings, do you teach your patients self-catheterization before discharge?
A. I do not.
Q. Do you know if that's commonly done --
A. I know --
Q. -- in the field in patients -- in surgeons doing autologous fascia?
A. There are many that do. I don't know if it's commonly done.
MR. SNELL: Do you want to

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take a break, Doctor?
- - -
(Whereupon, a brief recess was taken.)
- - -
(Whereupon, Exhibit Blaivas-17, 2012 Shaw Paper, was marked for identification.)
- - -
MS. FITZPATRICK: Also, Jerry had reached out, per your earlier questioning, to find out why some of these articles weren't included in that table and does have an answer for that, or at least an explanation from his -- I don't even know who it's from.
So if you want to ask him.
MR. SNELL: I'll let you do that, if you feel like it's necessary.
MS. FITZPATRICK: Okay. But it's on the record that there is an explanation for that. And it's

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your choice not to include that in your questioning.
MR. SNELL: That's fine.
MS. FITZPATRICK: He needs to amend his prior answer, because he does now know.
MR. SNELL: I'm not deposing somebody else, I'm deposing him.
MS. FITZPATRICK: I'm not giving you the explanation. All I'm saying is, he wants to correct -- he has the information available to answer a prior question, should you choose to ask him or not.
BY MR. SNELL:
Q. Are you ready, Doctor?
A. Uh-huh.
Q. So Exhibit 17 is a paper by Shaw, 2012. And I want to focus on the first page down at the bottom.
It says, The incidence of extrusion and erosion with midurethral sling is low.

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Do you see that?
A. I do.
Q. Is that consistent with the findings in your review paper, where you reported at Table -- give me a second here -- Table 3, complications of retropubic slings, that mesh exposure, total, was 2.2 percent?
A. Well, I prefer a number to a low, but you can interpret whether 2.1 is low. I mean --
Q. In your opinion, for the retropubic sling, Table 3, where you report 2.2 percent mesh exposure, that's low, correct?
A. It's low but significant.
Remember, in the beginning, I said there are those complications that happen so infrequently or of little consequence that you don't take them into consideration. Anything that happens 2.1 percent occurs often enough that a person should take that into consideration when making a decision.

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So in that regard, I don't consider it low.
Q. Stated conversely, 97.8 percent of the women do not have a mesh exposure, according to your calculations?
A. That's correct. Well, these are minimum data. We quoted a lot. We said that repeatedly in the paper, that this is the least number.
Q. This is the number that you were reliably able to calculate, correct?
MS. FITZPATRICK: Objection. Misstates the testimony.
THE WITNESS: I said -- very specifically, I said it's the minimum number that we calculated.
BY MR. SNELL:
Q. What you said, at the very end of the paper is, We calculated the overall risk of a serious complication or surgical failure to be 12.5 percent. We emphasize, though, that these data represent the absolute minimum rate of complications reported in the literature.

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The actual rate might be considerably higher.
Correct?
A. Right.
Q. So the number you were able to reliably calculate was 12.5 percent --
MS. FITZPATRICK: Objection.
BY MR. SNELL:
Q. -- correct?
A. Correct.
MS. FITZPATRICK: Misstates the testimony.
THE WITNESS: Also with the caveat --
MS. FITZPATRICK: Jerry, let me -- objection. Misstates the testimony.
Let me get my objections on the record.
BY MR. SNELL:
Q. Continue.
A. What I testified to before is somewhere between -- the minimum number is somewhere between 12.5 and 15

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percent.
Q. And that number wasn't reported in this paper, though; it was 12.5 percent?
A. No, it's reported in -- we calculated it a few different ways. And in the abstract, which is at the beginning of the paper, it gives a higher number.
Q. Why did you decide to include, in the conclusion, that the overall risk was 12.5 percent?
A. We calculated -- I'd have to see the paper. But we calculated it slightly differently.
And, I mean, quite honestly, the paper went back and forth for a number of different reviews. And I'm not confident that the -- both numbers are correct, they're just calculated differently.
They include different -- they include different complications, and I'd have to go through -- let me get the

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paper out.
See, here I say, Furthermore, at least one-third of the patients undergoing excision -- undergoing excision surgery developed recurrent stress incontinence. Considering the risk of refractory overactive bladder, fistulas and bowel perforations, among others, the overall risk of the negative outcome is about 15 percent.
I didn't include all of those things in the calculations in the conclusions.
I'm just looking -- so, for example, in this conclusion, it doesn't include the other rare complications like bowel -- like bowel injury and life-threatening sepsis and things like that.
So there -- they are both reasonably -- they are both correct, but they -- one includes more complications than the other.

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Q. Exhibit 17, we were looking at, on the second page --
A. We didn't get to anything yet on 17.
Q. I asked you about the first page.
A. Okay. Now, you're going to the second page. I'm sorry.
Q. Yes.
At the bottom it says, Over the last decade, synthetic materials have gradually become the primary material of choice for managing stress urinary incontinence in females.
Do you see that?
A. I do.
Q. And you acknowledge that, correct?
A. I do.
Q. Their popularity is related to the avoidance of a secondary harvesting site.
Do you see that?
A. Yes.

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Q. And that's a benefit of TVT, not having to have a secondary harvest site?
A. Correct.
Q. Decreased surgical time, that's a benefit as well?
A. Yes.
Q. And similar efficacy, we discussed in comparison to autologous slings, right?
A. Yes.
Q. It goes on to say, The safety and durability of TVT has been confirmed by various meta-analyses and long-term, up to 11.5 years, data.
Correct?
A. It says that. But as I've said repeatedly, I disagree with the safety part.
Q. This is a journal you find reliable, right, the Indian Journal of Urology?
A. This is actually the first article I've ever read from it. But --

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so I don't have -- I don't have an opinion about the journal.
Q. Well, this is a citation, this is a citation in your review paper. This is cited in your review paper.
A. I think this is an excellent review. You asked me about the journal.
Q. So you disagree with this statement made in this paper that was cited in your review?
MS. FITZPATRICK: Objection.
THE WITNESS: I disagree about the safety.
BY MR. SNELL:
Q. When we were looking at the mesh exposures in your paper on Table 5 for the retropubic -- I'm sorry, strike that.
When we were looking at the mesh exposure rate of 2.2 percent and the retropubic slings, as referenced in Table 3, such as TVT, were you able to ascertain whether the exposure was caused by surgical technique, patient factors,

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material factors or other potential reasons that could cause or lead to a mesh exposure?
A. I'm sorry, it depends where. Are you lumping all the exposures together or are you talking about vagina, bladder, urethra?
Q. Let's see here.
Let's -- so the most common mesh exposure for TVT that would be part of this 2.2 percent would be a vaginal mesh exposure, correct?
A. Yes.
Q. All right. For vaginal mesh exposures with a TVT, different factors like surgical technique, patient characteristics, material characteristics can have a bearing on that number, correct?
A. Yes.
Q. Did you attempt to ascertain to what degree surgical technique played into the rate of vaginal mesh exposures following TVT?

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A. There's no way to do that. The answer is no, there's no way to do that in a review.
Q. Okay. Is there a way to do -- strike that.
Is there a way to do that, though?
A. Well, I mean, yeah, I have an opinion about that, but it's not based on the review. It's just based on the technical aspects.
Q. When you say "the technical aspects," what do you mean?
A. Well, a bladder -- a bladder perforation -- I'm sorry, are we talking about exposures?
Q. Yes.
A. It's been well documented that bladder erosions, if you will, or -- bladder erosions are 26 times more likely with -- if there's a perforation at the time of the original implantation.
And it is my strong opinion that that is overwhelmingly a design

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problem that I discussed in the beginning, the design of the trocar and the surgical neck technique to pass it.
For vaginal -- so for bladder perforations, I think that's a design problem, primarily -- with the trocar and the design of the technique.
For vaginal perforations, I think it's primarily a problem of the mesh itself, the inflammatory reaction caused by the mesh.
And for urethral perforations, I think that's mostly -- it's mostly a combination of surgical technique and the design.
So that's my opinion.
Q. The bladder erosion rate that you report is 0.4 percent?
A. I'm sorry?
Q. The bladder erosion rate you report is 0.4 percent?
A. I need to just look at -- that's what it says, .4 percent.
Q. So by your calculation, 99.6

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percent of patients will not have a bladder erosion of the mesh, correct?
A. Sorry to do this, but I just have to check one thing in the paper.
That's what the -- I'm sorry, what was the question?
Q. By your calculation, 99.6 percent of patients will not have a bladder erosion of the mesh, correct?
A. Yes. Again, but I think that that's a gross underestimation because of the flawed nature of the methodology that looks at this stuff. But, yes.
Q. And for the 0.4 percent of the patients who have a bladder erosion of the mesh, in that small group, that's the one -- that's the group that you're referencing as pertinent to the Osborn paper?
A. Yes.
Q. And the Osborn paper didn't look at a cohort of women overall who didn't have complications compared to a

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cohort who did have complications, it was a series?
A. No, they looked at -- they did -- I'd have to see that paper. Do you have that? Because that's an important --
Q. I think I have it.
MR. SNELL: Let's mark that.
- - -
(Whereupon, Exhibit Blaivas-18, Osborn Paper, was marked for identification.)
- - -
BY MR. SNELL:
Q. Look at Number 18, it's the Osborn paper. This is a cohort of 77 women --
A. Give me just one second here.
Q. The Osborn study was a cohort of patients who had had a complication, correct?
A. I'm looking.
Sorry, it's taking me so

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long. I'm looking for the group they compare it to. You can't have an odds ratio without having a comparator group. And that's why I'm looking in the methods. It's been a while since I read this.

Q. As I read it, I didn't see a comparator group. They basically selected, out of the Vanderbilt electronics system, all female patients referred to urology for mesh exposure and perforation between January '03 and January 12th, correct?

A. Yes.

Q. So there was no non-complication cohort that they compared them against, at least as I read the study.

A. That's what I'm just checking.

I don't want to spend my more time on this. The authors concluded that there was a 26-fold increase. This is the same International Journal of

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Urology that we decided before was an acceptable journal.

So in a peer-review paper, they concluded there's a 26-fold increase chance of perforating the bladder or the vagina if there's a trocar injury at the time. My original reading of this satisfied the scientific scrutiny to allow me to conclude that.

But in the time allotted today, I would have to spend more time reading it to find it. Because there has to be a comparator, obviously, or you can't make an odds ratio without comparing it to something.

Q. As you sit here today, you can't point to the methodology by which a reliable odds ratio can be calculated, correct?

MS. FITZPATRICK: Objection.

THE WITNESS: It was peer reviewed. The peer-reviewed literature thought it was okay, and I thought it was okay when --

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I thought it was acceptable when I read it the first time. And I just don't -- I'd have to sit down and read the whole paper.

There may be one sentence in there that explains it.

BY MR. SNELL:

Q. Is the answer to my question no?

A. The answer to your question -- what is the question?

MS. FITZPATRICK: Objection. Asked and answered.

MR. SNELL: I'm going to move to strike.

BY MR. SNELL:

Q. As you sit here today, you can't identify the methodology by which this paper generated a reliable odds ratio?

MS. FITZPATRICK: Objection. Asked and answered.

BY MR. SNELL:

Q. Yes or no?

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MS. FITZPATRICK: Answer the question any way you need to give a full and complete answer.

MR. SNELL: Telling me what journal it was published in doesn't matter. That's not responsive.

MS. FITZPATRICK: It's the best answer that he can give.

MR. SNELL: It's a simple yes or no.

MS. FITZPATRICK: You answer the way you need to answer, Doctor.

THE WITNESS: I reviewed this paper previously, and I've actually -- I reviewed it a number of times before, and it satisfied my scientific scrutiny at the time. I do not have an independent recollection of what that was right now.

And I -- there are over 400 citations in -- just in this one

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article, and there's hundreds of others. I don't have an independent recollection of it right now. That's my answer to the question.
BY MR. SNELL:
Q. TVT utilizes a retropubic trocar passage, correct?
A. Yes.
Q. And was the retropubic trocar passage statistically significant?
A. I don't understand the question.
Q. Did the analysis of a retropubic trocar passage, like TVT, result in a significant statistically significant odds ratio in this study you cite to?
A. The perforation -- it was the perforation -- I don't understand the question.
They all had -- 100 percent of them had a passage. And if, during the passage, there was a perforation,

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there was a 26-fold increased chance of having a subsequent mesh erosion.
Q. Well, I understand you to be critical of the route, the retropubic passage of the trocars.
Are you not critical of that?
MS. FITZPATRICK: Objection.
THE WITNESS: I've already expressed an opinion that I am critical of that.
BY MR. SNELL:
Q. So what I'm asking you is, if you look at Table 3, they analyze retropubic trocar passage and they did not find a statistically significant increased odds ratio risk?
A. Table 3 you said?
Q. Yes.
A. I'm sorry, were these not all -- I'm sorry, I have to look at that.
Q. Do you see what I'm talking about, right?
A. Let me just -- in answer to

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the question, it was the perforation of the bladder or the vagina that had the increased odds ratio, not the mechanism, not the technique.
Q. The retropubic trocar passage did not show a statistically significant increased risk, correct?
MS. FITZPATRICK: Objection.
THE WITNESS: No, it did not.
MS. FITZPATRICK: Objection.
THE WITNESS: Yes, it did not, excuse me.
BY MR. SNELL:
Q. The P value was .9?
A. Correct.
Q. And you and I can agree that a P value of .9 is nowhere near close to being statistically significant, correct?
A. Correct.
Q. And what these authors also reported, same page, about the trocar injury is, it says, The limitations of this present small retrospective study

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make it impossible to conclusively state there is a direct causal link between trocar injuries and mesh perforation.
Do you see that?
A. I agree with that, yes.
Q. Clearly, there are many potential confounding variables, such as surgeon experience and many unknown factors that might have contributed to this result. Further research in this area is required.
Correct?
A. Yes. But all that's saying is they were too small numbers to make -- the numbers -- these are two confounding statistical -- or statements.
The problem is that there were -- the number was too small, there weren't enough TOTs versus TVTs to show a statistical significance, number one.
But, more importantly, it's more likely that the TVT -- the TOT trocars were vaginal perforations and the TVT were bladder or urethra perforations,

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so it's almost like comparing apples and oranges.

So you'd have to separate out -- in order to conclude, you'd have to see -- you'd have to compare perforations of the bladder, TOT, versus TVT, and perforations of the vagina, TOT versus TVT. And it's clearly, with four groups, this number of patients is going to be way too small to show any kind of statistical significance.

But the salient point is that perforation of the bladder -- perforation of the bladder or vagina is a risk factor for subsequent erosion. And that's the point that I made.

Q. What are the patient risk factors for a mesh exposure?

A. I mean, I think probably the most significant is probably, I'm sure is the health of the vaginal wall, if you will. So scarring and vaginal atrophy is number one, I would think.

Then there's other risk

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factors like, you know, I think diabetes.

I mean, the other -- all of the other purported risk factors, I think, are just statistical oddities. It doesn't make sense that age -- some studies show that younger age is a risk factor, others have shown that older age.

But I think the two important ones are, I'm lumping together, vaginal scarring and atrophy. And I think I said diabetes.

Q. Is it safe to say, Doctor, that any study that concludes that TVT is safe is a study you disagree with?

MS. FITZPATRICK: Objection.

THE WITNESS: No. What I would say is that I don't like the term "safe," okay. I prefer a number.

And if you take a number, one person -- like, nobody disagrees -- so far as I can see, there is no disagreement about what the complication rate is, or

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there's very little disagreement about what the complication rate is.

What the disagreement is about is whether, you know, 5 percent is safe. And it seems to me that the judgment as to whether a percentage is safe should be the province of the patient, mostly, not the doctor.

So I'd rather have a number than safe or unsafe.

BY MR. SNELL:

Q. And different patients have different risk adversity levels, correct?

A. Correct.

MS. FITZPATRICK: Objection.

BY MR. SNELL:

Q. Some are smokers, correct?

A. Correct.

MS. FITZPATRICK: Objection.

BY MR. SNELL:

Q. And everyone knows that smoking is terribly bad for you, correct?

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MS. FITZPATRICK: Objection.

THE WITNESS: Yes.

BY MR. SNELL:

Q. When you reported that in the TVT group, in your paper, refractory pain greater than six weeks was 1.8 percent --

A. That's in the -- what's the question, I'm sorry?

Q. So I want to go to that 1.8 percent for refractory pain.

A. Where are you now?

Q. Still Table 3 of your review paper.

A. All right.

Q. So you reported that in the TVT group, refractory pain greater than 6 weeks occurred in 1.8 percent of women, correct?

A. Yes.

Q. So that means that 98.2 percent of women would not have the risk of refractory pain greater than six weeks, according to your calculation,

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correct?
MS. FITZPATRICK: Objection.
THE WITNESS: These are --
MS. FITZPATRICK: Objection to the form of that question.
THE WITNESS: These are reports of a terribly flawed literature that doesn't seek -- that doesn't even ask about refractory pain, okay?
And so when we did our calculations another way, okay, which is what we reported in the summary, the incidence of refractory pain was something like 4 percent.
Because then we did it another way, and we took all the -- these are the reports in the literature. These do not reflect our calculations. These are simply taking all the reports in the literature, which we -- and we make the point over and over

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again in the paper that those reports, when -- with respect to pain in particular are grossly underreported.
So all we're doing is -- in this section, reviewing a badly done scientific -- badly done scientific study with respect to pain and we're reporting that.
But our conclusion in this paper is that the actual incidence of refractory pain is more like, I may get the exact number wrong, but something on the order of magnitude of 4 percent, not 1.1 percent, or whatever.
BY MR. SNELL:
Q. Well, that's because you lumped, in your conclusion, all of the different midurethral slings together, correct?
A. Yes, we did.
MS. FITZPATRICK: Can you read back that question?

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- - -
(Whereupon, the court reporter read the following part of the record:
"Question: Well, that's because you lumped, in your conclusion, all of the different midurethral slings together, correct?")
- - -
BY MR. SNELL:
Q. And your answer is yes, correct?
A. Yes. Well, I mean, let's not be -- when you say -- we did -- I hate when I nitpick. Ask the question again, if you don't mind.
Q. I think you answered it.
The 4.1 percent that you report in the conclusions of the abstract --
A. Yeah.
Q. -- includes your lumping together of all midurethral slings?

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A. Yes. The answer to that is yes.
Q. And I am focused on TVT.
TVT, you reported 1.8 percent in the retropubic slings, Table 3, right?
A. With the -- you already asked me that, and I answered it with the caveat that the -- well, I've already answered it and gave you my caveat.
Q. So in the retropubic sling group, we can agree that according to the numbers you reported in Table 3, specific to retropubics, 98.2 percent of women did not have pain defined as lasting greater than six weeks, correct?
A. No. We included the ones that did have pain. And I do not believe you can conclude that if it did not -- if they didn't record pain in the paper that they did not have pain. I think those are different statements.
Q. For the 1.8 percent of the retropubic TVT patients who had

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refractory pain greater than six weeks -- strike that. Let me back up.

Why did you define refractory pain as pain lasting more than six weeks?

A. We didn't. That's what the papers did.

Q. Fair enough.

Of the 1.8 percent of the TVT women who had refractory pain lasting greater than six weeks -- and just so we're specific, that total, 42 women out of 200 -- strike that.

I'll get this right.

In order to calculate the 1.8 percent of women with TVT who had refractory pain greater than six weeks, that number of women was 42 out of a cohort of 2,328 patients, correct?

A. That's correct.

Q. Of that 1.8 percent of the TVT women who had refractory pain lasting greater than six weeks, how many of them had resolution at six months?

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A. Almost none of the -- almost none of the papers even mentioned that, nor did they have any mechanism for accruing that data.

And, if you notice, when it comes to -- for a lot of this stuff, look at the numbers. The urethral obstruction the number of patients is 16,000, 6,000, 8,000, I'm just reading down the column, 7,900.

When you come to pain, the ones that are even asked about pain, are only 2,000 patients; whereas the ones that even asked about mesh exposure was 8,000, pelvic organ prolapse, 13,000.

So this makes my point that few of the studies were -- even mentioned pain, even had a way of assessing pain.

Q. Few of the studies that you decided would be reported in this paper, correct?

MS. FITZPATRICK: Objection.

THE WITNESS: We did a literature search, and the

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literature search included, I would say, for practical purposes, the overwhelming majority of papers that are relevant to this topic.

BY MR. SNELL:

Q. Do you know how many papers there have been published on TVT in particular --

A. No, I don't.

Q. -- either randomized control trials, cohort studies, retrospective, prospective?

A. I don't. But I know almost all of them are sponsored by Ethicon, or most of them were sponsored by Ethicon.

Q. What's your methodology for that statement?

MS. FITZPATRICK: Objection to the term "methodology."

THE WITNESS: The methodology is an article we are researching right now, where we have looked at just that.

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We are taking all -- I'm sorry, this isn't specific to TVT, but it is specific to efficacy trials. I'll retract that. I don't want to -- if I can.

BY MR. SNELL:

Q. I think you ought to, because I don't think it's accurate.

If you look at the Cochrane review that was just published this year by Ford that included over 70 randomized control trials, the vast majority of which included TVT, that we're talking about here today, can you tell me that the majority of those RCTs that were sponsored by Ethicon?

MS. FITZPATRICK: Objection.

THE WITNESS: I can tell you, on average, one-third are sponsored by industry, one-third of -- have at least one author who has a conflict of interest because he's either a paid speaker or a consultant or an ad board for

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industry, and then there's only one-third of the papers that we've reviewed so far have no conflict of interest.
BY MR. SNELL:
Q. Have you done that analysis specific to TVT?
A. No. But we have that data. I'll break it down for you.
Q. Have you ever taken money from industry?
A. Not --
Q. From Ethicon, Bard, AMS, any manufacturers of the mesh?
A. I've never -- I have been consultants to them on an ad board. I've never -- except for very, very early in my career, and then I stopped, I never gave a lecture, I never did -- had anything to do with promotional activity. So for practical purposes, no.
Q. Do you believe that the fact that someone gets money from industry for consulting, providing professional

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opinions, that that person is biased such that you can't believe the data they report in a study?
A. Not -- I think that needs to be disclosed, and it's for the reader to -- it's for the reader to decide. And I think there are some that are tainted and some that aren't.
But I wouldn't make a generic statement. But I think the conflict of interest is there. And the whole point of conflict of interest is for each person to decide for themselves how believable it is.
Q. In that refractory pain group of 1.8 percent of the TVT women who had pain at more than six weeks, do you know how many of those patients had total or partial resolution at any time period, like 12 months, 24 months or --
A. I know there are a few -- there were a few articles, mostly the ones that were done by the NIH sponsored network, that actually did have some of

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that in it; most of them did not.
Q. As you sit here today, do you know, of the 1.8 percent of women who had refractory pain beyond six weeks, what percentage of those patients had that pain for any duration of time?
MS. FITZPATRICK: Objection to form.
THE WITNESS: I do know that I personally, particularly, looked to find that, and I didn't -- and the paper -- in the papers that I reviewed, I could not find that information.
Except for in one -- I'm sorry, I don't remember the particulars. There was one study that had some information about that.
BY MR. SNELL:
Q. Do you recall those data, what they reported?
A. I don't. But I could -- it wouldn't take me long to find it, if you

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want to use your time for me to do that.
Q. You agree there is a difference between potential bias and actual bias?
A. No, I think bias is bias. No, I think there's bias. And I'm not sure what you mean by that.
What do you mean by "potential bias"?
Q. Well, I thought you said before that you were not willing to make a blanket statement that just because someone received money that their results were biased such that you could not trust and believe what you read?
A. That relates to conflict of interest. So a conflict of interest -- a conflict of interest is a perception that there might be bias. So to that extent, if that's what you mean by potential bias, then, of course, there's a difference.
Q. The fact that you're serving as an expert and getting money from

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plaintiffs' lawyers, does that make you conflicted?
MS. FITZPATRICK: Objection.
THE WITNESS: I don't feel conflicted, but it's not for me to say. I'm certainly -- my peers, people in the audience, each are entitled to their own opinion.
BY MR. SNELL:
Q. Because you accept money from the plaintiffs' lawyers in the mesh litigation, are you biased?
MS. FITZPATRICK: Objection.
THE WITNESS: I don't believe I am.
- - -
(Whereupon, Exhibit Blaivas-19, 2010 European Urology Journal Review and Meta-Analysis, Novara, was marked for identification.)
- - -
BY MR. SNELL:
Q. I've handed you Exhibit

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Number 19.
This is updated systematic review and meta-analysis by Novara, et al., published 2010 in the European Urology Journal.
You're familiar with this paper?
A. I am. Well, I've read it.
Q. In this meta-analysis, they looked for a randomized trial similar to the way the AUA went about formulating their stress incontinence guidelines?
A. The stress incontinence guidelines were not based entirely on randomized controlled trials, I don't think.
Q. That's fair.
In any event, in this Novara meta-analysis, they reported that when you looked at midurethral slings versus pubovaginal slings, there were similar cure rates.
Do you see that?
A. Yes.

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Q. And we've already covered that.
And it says, Although the latter -- and they're referring to the pubovaginal slings -- were slightly more likely to experience storage lower urinary tract symptoms.
Do you see that?
A. I do.
Q. What are storage lower urinary tract symptoms?
A. It can be urinary frequency, urgency, urge incontinence, stress incontinence, possibly pain.
Q. Is that an accurate statement, in your opinion, that pubovaginal slings have slightly more storage lower urinary tract infections than a midurethral sling?
A. Not in my hands, they don't.
Q. Recognizing that you can't do all the incontinent sling surgeries in this continent or the world, in other surgeons' hands in the general

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population, is that a fair statement?
A. I don't think it is.
Q. Why not?
A. Because as I alluded to when I -- when we talked about the paper that came out of Duke that you asked me to look at, before looking at autologous slings -- it didn't come out of Duke, it quoted -- the paper in the Japanese Journal of Urology, and I said, well, that technique, in my judgment, would -- with that technique, I would predict they would have more complications.
So what you're basically doing is, you're comparing an operation that, for practical purposes, everybody on the planet does exactly the same way, okay? And doing it that way, they have, in my opinion, an unacceptably high complication rate that would make them not choose the surgery if they knew they were going to have it.
So you're comparing an operation that is very consistent in both

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its -- pretty consistent in its efficacy, surgical technique and the complication rates; you're comparing that to an operation where kind of everybody does it whatever way they want, as you alluded to before.

And so, to me, that's an ultimately unfair comparison.

Q. Just so we're clear on the record, too, I know you were -- when you talked about a procedure that everybody does whichever way they want, you were referring the autologous pubovaginal sling, correct?

A. Yes.

Q. And that is actually one of the downfalls of the way that procedure can be done, in that it can be done any which way and it is done that way, correct?

MS. FITZPATRICK: Objection.

THE WITNESS: If you consider a downside to do an operation that, for practical

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purposes, causes none of the serious complications that the TVT does, for practical purposes, never causes mesh erosions, never -- almost never causes -- we're talking about the autologous sling -- refractory pain, never causes any, if it does cause -- if there is a fistula, if there is a urethral obstruction, it's very straightforward to take care of. The TVT has none of those characteristics.

You're right, it's done the same way by most people all the time. But that same way, in my judgment, results in an unacceptably high serious complication rate.

So I don't think it's -- I think it's a benefit to let people do it in a way that causes little or no harm.

BY MR. SNELL:

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Q. In the autologous slings, the fact that surgeons can do it any which way they want to, in your opinion, leads to unacceptably high urinary voiding and retention problems, right?

A. The consequence of that is very easy to fix. The consequences are the same complications with mesh complications, it leads to at least one or more operations, and often with unsatisfactory results.

Q. The statement you just made, can you elaborate on that? Because I don't quite understand what you said.

You're not saying, obviously, that every woman with a TVT is going to have a complication?

A. No.

Q. Are you saying that every woman who has a TVT who has a complication like mesh exposure is going to have to have a surgery?

A. Most.

Q. Are you saying that every

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woman who has TVT who has a mesh exposure that's surgically operated on is not going to get better?

A. Many will require a second operation to fix -- many of them will have recurring stress incontinence. And then that stress incontinence, I believe, is more difficult to fix because of the mesh. And many of them will develop pain afterwards.

And that will not be accounted for in the tables that look at that stuff. It's all in the text.

Q. When you say these words like many, many, many, I don't see anywhere in your review paper where you're reporting 10 percent of women with TVT are having pain lasting more than, you know, six weeks.

A. I said we reported that 4-point-something of women have refractory pain that -- by refractory pain, refractory treatment, they have the pain, they have treatment that doesn't

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get better. And that a large number of those, I can't tell you how many, are TVTs, because TVTs were the most commonly done. And my own personal experience would support that.

Q. I don't want to get into the 4.1 percent, because I want to focus on, specifically, the retropubic, the TVT, because you broke it out and, clearly, there's a difference in the rate of this pain lasting more than six weeks between retropubic and transobturator, right?

A. In the table, yes.

And, again -- but remember the table is -- I keep making the distinction between the table, which is the reported literature, and then our methodology took all the known cases in the literature, including -- so every single patient that occurs in the literature, okay, is the denominator.

The numerator are all the patients with the complication in the -- all the patients with the complication in

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the reported series that don't look at complications and all the patients in the literature that -- the case reports and case series with the complication.

So if there were two -- so we added all those together, took the numerator as all the complications and the denominator as all the patients reported in the literature, and that gave us a much higher -- that gave us a higher complication rate.

Q. In your own publications that you've written about autologous fascial slings, is it fair to say if you did not mention that your patients had pain beyond six weeks, that it didn't occur?

A. No. I mean, I wish it were. There's some -- I mean, quite honestly, I don't mean to be self-serving, but we did try to capture all the data.

So if someone did say -- if we knew about it, we would include it. But we -- you know, especially in the old

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time, we were no better in capturing these things. So if a person -- I mean, take, for example, death, okay? I have the only death reported in the entire world literature in a study of slings. So, I mean there's only one death reported in the entire world literature, that I'm aware of, going back 40-plus years.

And just to be fair, that was a lady that died one month after surgery of a totally unrelated -- of a totally unrelated thing. But because she died within the 30 days, we included it as a death.

I am personally aware of patients that had -- of patients that died after surgery with famous surgeons that I know participate in clinical trials, okay, personally, I know it personally. They never appeared in any series. I don't know why.

So my point is, all of these things are just grossly underreported.

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Q. For pubovaginal slings, have there been patients who have died during the procedure, after the procedure, but it hasn't been reported in the literature?

A. For autologous slings?

Q. Yes.

A. I don't know. But I would say almost categorically the answer has to be yes. I doubt if anybody ever died during surgery. But I'm sure that someone died in the perioperative period.

Q. There's -- surgeons don't report their complications with an autologous sling to the FDA MAUDE database, correct?

A. Correct.

Q. You've never done that, correct?

A. There's no mechanism for that. It's not a device.

Q. And because of limitations in the medical literature pre-2000, the true scope and volume of complications

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with pubovaginal slings was not reported accurately, correct?
A. I think the serious complications would have been. We report, all these cases -- all these case series of complications after synthetic slings, if patients with pubovaginal slings had those kinds of complications, I'm confident they would have been reported in the literature. They just didn't exist.
Q. Did surgeons track and report pain and dyspareunia frequently in the medical literature from the 1980s and 1990s?
A. I don't believe so.
Q. Why is that?
A. I mean, quite honestly, I think it's kind of an inherent bias that we all have, that you don't really -- I think it's just really a -- I think it's just a bias.
I think that the patients that -- I really meant what I said

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before. I think people with this bad pain and people with dyspareunia, I mean, if they complain to the original surgeon, more likely than not, especially in answer to your question back then, they would say, well, you know, it will probably get better, don't worry about it or take this pain medicine.
We don't have a lot to do about it. And then over time, the patients just come to accept the fact, the realization that the surgeon doesn't care much about those things. He cares more about things he can measure. And then the patient tells some other doctor about it, and says, I don't know if I can go back and see the surgeon. And the net result is the patients just give up and don't even tell -- I've seen hundreds of people like that.
And I'm not just -- this isn't something I'm plucking out of the sky. There's -- some of papers we referred to in our Nature review article

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make the same point. Women just give up. Nobody is paying attention, so they say, well, I guess I'll just have to get used to this.
Q. In the Novara meta-analysis, they also reported that the pubovaginal sling had a higher reoperation rate than the midurethral sling, based on the randomized control trials.
Is that something you acknowledge and agree with?
MS. FITZPATRICK: Objection.
THE WITNESS: This is not fresh in mind. When I reviewed this article, what sticks out in my mind is in this paragraph where it says evidence synthesis, the statements are contradictory.
I do not have any confidence that they -- that they did the analysis correctly.
And, I'm sorry, I hope you don't want me to take the time now, but we can. But basically,

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they say, well, this operation had more complications than this and less than this, and they make one statement; and then they make another statement that says something else comparing one operation to another one.
But when you look at them in their totality -- what I actually did, I actually wrote them out. And I said, okay, this is greater than this and this is greater than that and this is greater than that. And it turned out that there were contradictions.
It was -- the logic was incorrect. You can't -- you can't have a better outcome in pubovaginal slings in one sentence and lesser outcomes in another, but it did.
BY MR. SNELL:
Q. I'm focused on the midurethral sling versus pubovaginal.

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It acknowledged that the efficacy was similar?
A. Yes.
Q. And you've said that before, correct?
A. I agree.
Q. No argument whatsoever about that, correct?
A. None.
Q. And in the analysis of all the various complications, they report that there was a statistically significant increase in the likelihood to experience storage lower urinary tract symptoms with the pubovaginal sling, and then the pubovaginal sling also had a higher reoperation rate, correct?
A. Yes.
Q. That's not contradictory?
A. No, it isn't.
But when I went through -- see -- I'm sorry, I can't go through it now.
But my conclusion from this

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paper was that it was suspect, because it -- when I went through it, it didn't -- they were mutually contradictory statements in here in the conclusions.

- - -

(Whereupon, Exhibit Blaivas-20, Review and Meta-Analysis, Society of Gynecologic Surgeons, was marked for identification.)

- - -

BY MR. SNELL:
Q. Before we get into that, I want to ask you just a couple of general questions. Let me know when I have your attention.
If there was a lower reoperation rate with TVT compared to a pubovaginal sling, you would acknowledge that would be a benefit to TVT?
A. Not necessarily -- no, I wouldn't, actually.
Q. Why not?

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A. Because the complications that occur with the TVT, even if it's a lower rate of reoperation, the success rate after -- the success rate of operations on autologous slings is very, very, very high in my -- in my experience, for sure.
And for practical purposes, there are no -- like, none, zero, lifestyle-altering complications after autologous slings.
So if there's a higher rate -- if, and this is hypothetical, if there was a higher rate after autologous slings but all of the complications were -- had a satisfactory outcome and there was a lower rate for synthetic slings but many of the outcomes were not satisfactory, I would not consider that an advantage.
And that, I believe, what the facts -- and that's the way I think it is.
Q. Do you acknowledge the rate

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of reoperation with autologous slings is higher than midurethral slings, it's just the severity of those conditions is worse, in your opinion, with the TVT?
MS. FITZPATRICK: Objection.
THE WITNESS: I acknowledge that the literature says that. And I haven't looked at it in enough detail to see whether or not I think the methodology would support it.
BY MR. SNELL:
Q. Have you read this paper that we marked as Exhibit 20, it's a systematic review and meta-analysis by the Society of Gynecologic Surgeons?
A. This is one of the papers I read a number of times, but it's -- it's been a long time and I've read probably over a thousand papers by now on this stuff, and so I can't remember for sure which is which.
Let me just take a -- ask your question, and I'll see if I need to

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take a look.
Q. The systematic -- the Society of Gynecologic Surgeons, that's a well respected group within the field of the female, you know, pelvic health?
A. I respect them, yes.
Q. Did you ever belong to SGS?
A. No, I think it's only for gynecologists.
Q. I don't think so.
A. It always used to be.
Q. Okay.
A. Maybe it's changed now, but --
Q. SUFU, is that only for urologists?
A. No, that's for --
Q. That's both?
A. Yes.
Q. In this, they went through and did a systematic review and meta-analysis, correct?
A. Yes.
Q. And that is a

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methodologically rigorous way of --
A. You know what, I'm sorry, this is 2014. I definitely read an article like this. I'm not sure if there was an earlier version than this, because it looks pretty recent.
Q. It says at the bottom it was presented at the 39th annual SGS meeting in 2013.
A. That, I saw.
Q. And it was published in 2014, in January.
A. Yeah, I don't -- my gut says this is the one I reviewed, but I'm not 100 percent sure.
Q. Well, I don't believe that this paper was captured in your review article either, in the list of citations. But that's a whole other issue.
Let me ask you this: So a systematic review of meta-analysis by the Society of Gynecologic Surgeons, that's a methodologically recognized way of assessing large amounts of data, correct?

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A. Yes.
Q. And I think the authors reported that they had no conflict of interest in this.
Do you see that?
A. Well, I'll take your word for it.
Q. I wouldn't misrepresent. It's down at the bottom.
Do you see where I'm at?
A. Yes.
Q. Do you recognize any of those names, Vivian Sung, Tom Wheeler?
A. A few of them, but most of them, no.
Q. Do you understand that SGS has a systematic -- a designated group of people who are to systematically review the literature?
A. No, I wasn't aware of that.
Q. What they did is they systematically reviewed the English language randomized control trials from 1990 through April 2013, with a minimum

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of 12 months follow up.
Do you see that?
A. Uh-huh.
Q. Is that a yes?
A. Yes.
Q. In their results, they say -- if you look at the very bottom here, for pubovaginal slings versus midurethral slings, meta-analysis of subjective cure favored the midurethral sling.
A. Okay.
Q. Therefore, we recommend midurethral sling.
Do you see that?
A. Yes.
Q. You will acknowledge that there are randomized control trials that report a significantly better subjective cure for midurethral sling compared to midurethral sling?
A. Say that again.
Q. You acknowledge that there are randomized control trials that report

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an improvement in subjective cure for midurethral sling compared to pubovaginal sling, correct?
A. I'm sorry, you said it quite nicely this time, but I didn't hear it, not because I wasn't paying attention.
MR. SNELL: Can you read it back?
- - -
(Whereupon, the court reporter read the following part of the record:
"Question: You acknowledge that there are randomized control trials that report an improvement in subjective cure for midurethral sling compared to pubovaginal sling, correct?")
- - -
THE WITNESS: Well, if they report it, I suppose they do. I'm not familiar with the particulars of the individual papers, though.
BY MR. SNELL:

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Q. A little further down, they actually looked at, also, mini slings versus full-length midurethral slings like TVT. And the meta-analysis showed objective and subjective cure, both favored the full length slings, like TVT.
Do you see that?
A. Where is that?
Q. It's the last four lines of the results that we were just looking at.
And as a result they say, Therefore, we recommend the full-length midurethral sling.
Do you see that?
A. Yes.
Q. And have you seen data that's consistent with their analysis?
A. With that part, yes.
This is coming back to me. I definitely -- I have seen this. I know it's -- if it's not in our paper, it's in the reliance list. So this is -- remember, I said -- I know I've read this a number of times.

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And I remember, I certainly didn't agree with favoring the midurethral slings over pubovaginal slings. And it's the same -- it's really the same objection I cited before. I mean, I think they're methodologically flawed.
Q. Well, you would not disagree that, based on their systematic review, methodology, the way they crunched the randomized control trials, that the midurethral slings had a better subjective cure than pubovaginal slings, right?
A. I don't deny that that's what they concluded.
Q. Well, I think this is -- let me ask you this: I mean, you haven't tried to replicate what they did, to show that they were wrong in their finding that there was better subjective cure with midurethral sling compared to pubovaginal, have you?
A. No. The problem is, as I

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mentioned before --
Q. Did you do that, yes or no; then you can --
A. Did I try to do what?
Q. Did you try to replicate what they did, where they analyzed the randomized control trials for the midurethral slings and found that subjective cure was better for midurethral sling than the pubovaginal sling?
A. I did not try to do that.
Q. So you can't sit here and say, one way or the other, that their reporting is not accurate based on the data, correct?
MS. FITZPATRICK: Objection.
THE WITNESS: I would need to review the paper in more detail to answer that question.
BY MR. SNELL:
Q. One thing that they did in this study, if you want to look really quick at Figure 1, they didn't just

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consider the randomized control trials, they also looked at nonrandomized control trials for adverse events, complications; not just for midurethral slings but for pubovaginal and Burch.
Do you see that?
A. This is Table 1? Let me see.
Q. Figure 1.
A. Well, let me just --
Q. Can I get an answer to my question?
A. They talk about randomized control trials, but, in fact, there are only four of -- excuse me, five of autologous fascial slings. And the numbers -- I mean, the number of patients is low, 21 versus 20, 28 versus 21, 79 versus 50.
I mean, these are just not -- it's the best you can do, but they are hardly convincing to me. I mean, there's thousands and thousands and thousands of these things done, and we're

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talking about a total of, like, 150 patients or something.
This is just -- it's unconvincing data to me.
MR. SNELL: I'm going to respectfully move to strike.
MS. FITZPATRICK: Objection.
MR. SNELL: That's fine.
BY MR. SNELL:
Q. My question was just this: If you look at Figure 1 --
A. Figure 1 is which? Let me look at Figure 1. I was looking at the table.
Q. It's on the second page.
A. Okay.
Q. My question was, if you look at what they did, they looked at not only randomized control trials, but they also looked at nonrandomized control trials for the Burch, midurethral sling and all the different surgeries, correct?
A. Yes, they did.
Q. If you'd go to Table 3. Let

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me know when you're there.
That's when they report on rates of adverse events?
A. Okay.
Q. And they included data from not just the randomized trials but also other studies.
Do you see that?
A. Yes.
Q. You see for dyspareunia --
A. Yes.
Q. -- pubovaginal sling was reported to have a .99 percent rate of dyspareunia?
A. Yes.
Q. Is that consistent or inconsistent with your understanding of the literature?
A. The question is .99 --
Q. Basically, 1 percent. They reported a 1 percent rate of dyspareunia with pubovaginal sling?
A. And the question is?
Q. Is that consistent or

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inconsistent with your opinion as to what the rate of dyspareunia is after pubovaginal --
A. I would accept that.
Q. Do you have the AUA guidelines handy?
A. What?
Q. The tables we were just looking at before.
A. I would not say handy, but it's in my pile here.
MS. FITZPATRICK: This one?
MR. SNELL: Yes.
THE WITNESS: While I'm looking for it, though, it has a .16 incidence of dyspareunia for obturator sling in the same table, which is -- I mean, to me, which is ridiculously low compared to other studies in the literature.
BY MR. SNELL:
Q. Let's go back to Page A16 with the no prolapse. Let's look at autologous fascial slings without bone

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anchors.
Do you see where I'm at?
A. Which table?
Q. A16 in the back, no prolapse.
A. Okay.
Q. So we're looking at the AUA stress incontinence guideline table, autologous fascial without bone anchors, A16.
You all actually reported a 10 percent rate of pain and an 8 percent rate of sexual dysfunction following --
A. Where is this? Appendix A16 has lots of different pages.
MR. ROSENBLATT: The entire appendix is A16.
BY MR. SNELL:
Q. So autologous fascial without bone anchors is the category that would fall into what you do, right?
A. Yes.
Q. And you all reported a 10 percent rate of pain with the autologous

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fascial sling without bone anchors and an 8 percent rate of sexual dysfunction, correct?
A. That's what it says here.
Q. If you look at the -- look back at the table with the SGS systematic review.
A. Yes.
Q. You see with the exposure risk --
A. Where is that?
Q. Two down.
So we looked at dyspareunia?
A. For erosion exposure, okay.
Q. Let's just stick -- let's go in order.
We looked at dyspareunia.
For return to operating room for erosion, pubovaginal sling had 1.6; retropubic sling, like TVT, had 1.9 percent, correct?
A. No. Are you talking about exposure or erosion?
Q. Return to the operating room

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for erosion.
A. Yes.
Q. Pubovaginal sling had a 1.6 rate, retropubic TVT had 1.9 percent rate, correct?
A. That's what it says there.
Q. There are studies reporting that women who have pubovaginal slings do need to, in some circumstances, return to the OR for erosion?
A. That's what it says here.
Q. For exposure, the rate of retropubic TVT exposure was 1.4 percent.
Do you see that?
A. I do.
Q. Does that number seem about right to you?
A. I mean, it's in the ballpark, single-digit percent.
Q. It's based on 29 different studies, correct?
A. Yes.
Q. Over 5,000 patients assessed, correct?

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A. Yes.
Q. Pubovaginal sling, ten studies, the rate of exposure was 5.4 percent.
Do you see that?
A. Yes, I do.
Q. And what types of exposures occur with pubovaginal slings?
A. To be quite honest, I've never heard of one. In 40 years, I've never heard of one. Nobody has ever told me they had one.
I have no -- I don't have a good adjective for this -- I have no idea where that came from, and I'll have to look at the papers.
And, if that's true --
Q. They reference ten studies, 48 events.
A. I'm going to look at those studies. You want to show me those studies? I think that both of those statements are -- it's just incredulous.
I mean, I edited a journal

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for 25 years. I've practiced this. I've given, probably, thousands of lectures, we've talked about complications. And for something to occur in 1 of 20 people and me never hearing of it, I think is -- I just don't even know what to say about that.

Q. Could it be because of surgeons doing pubovaginal slings differently than you do, though?

A. I've lectured -- I mean, I've interacted with thousands, thousands of urologists and gynecologists worldwide. If 1 out of 20 patients had this complication, it's inconceivable to me that no one would have ever asked a question, how do you deal with an erosion.

I can't walk down the street at the AUA or SUFU without someone asking my advice about how to deal with a mesh erosion. It's just -- which happens, according to this table, 20 percent of the time it happens with a pubovaginal

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sling.

The only thing I can think of -- I don't even -- I'll just see the papers and formulate an opinion.

Q. In your Table 3, we looked at your overall rate of exposure erosion was 2.2 percent for the TVT.

That's not much different than the 1.4 percent for this table?

A. I accept it. I never said it's more than, you know, low single digit percent. I wouldn't be surprised if it's 3 to 4 percent. I wouldn't be surprised if it's 2 percent. But I cannot fathom 5 percent.

Q. You see up at the top, for bleeding complications, particularly the transfusion and hematoma, pubovaginal slings have the highest rates, 1.9 percent and 2.2 percent respectively.

Do you see that?

A. I have to say, these numbers seem high to me. But I'm not going to argue with a -- to hematoma or a -- I'd

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have to look at these papers to comment on it.

To say the least, I'm -- that does not comport with any experience I've had.

Q. Understanding -- you told me you have some of the lowest rates, apparently, in the world with pubovaginal.

But other people -- other people out there doing pubovaginal sling, do you believe that they, in general, have higher rates of complications than in your hands?

A. Probably. But I've lectured on this for 40 years. People don't say, hey, how do you control hemorrhage? It's just -- to me, something is wrong with this. I've already said it. I don't need to say it again.

Q. On the next page, you see where -- let's look at ureteral injury, right?

Retropubic was zero and that

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was based on one study; pubovaginal was exceptionably low, too, with 0.81 percent, correct?

A. Yes.

Q. One event out of 567, correct?

A. Uh-huh.

Q. Have you ever injured the ureter during pubovaginal sling?

A. No. I've seen one -- I haven't personally, and I've seen one in my career.

Q. I believe your paper reports that the rate with the TVT of ureteral injury is exceptionally low, below 1 percent as well?

A. Yes.

Q. Is that your opinion as well?

A. Yes.

Q. Overactive bladder urgency, pubovaginal had the highest rate, 8.6 percent, correct?

A. Yep.

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Q. So at least according to these data we've been reviewing so far, TVT does not look to have higher complication rates than pubovaginal sling, correct?
A. Retropubic here is what?
Q. TVT. Burch has its own category, so does the transobturator and mini sling.
The nice thing about this paper, Doctor, is you see they break it out, actually, specific.
Coming back to my question, the data we've been looking at in this systematic review by the SGS does not show the TVT to have a higher risk of complications than the pubovaginal sling, correct?
A. These things don't say that.
But, again, the reasons I said before, I disagree with the -- I disagree with the -- some of these results. Whatever, I already talked about it.

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Q. So urgency, pubovaginal, again, had the highest rate, correct?
A. I don't know if that's statistically significant, but 8.6 versus -- you know, 55 patients versus 374.
You'd have to just do the math, but it's not very impressive.
Q. Retention lasting less than six weeks; so the TVT was 3.1 percent and the pubovaginal was 12 percent, correct?
A. Where is that?
Q. That's the next -- I'm just going in order, the very bottom here.
Retention lasting less than six weeks, TVT, 3.1 percent, pubovaginal sling, 12 percent, correct?
A. I don't -- I just see mini sling, retropubic and obturator.
Q. Let me just make sure we're on the same page.
Retropubic here, 3.1. If you flip over, the table continues.
A. Okay.

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Q. So TVT, 3.1 percent, pubovaginal, 12 percent, correct?
A. Yes.
Q. And you'd agree that with regard to retention lasting less than six weeks, that's consistent with the overall literature that the pubovaginal sling does have a higher rate of retention than TVT?
A. With the caveats I said before, yes.
Q. And for retention lasting longer than six weeks, the TVT was 2.7 percent, pubovaginal was 7.5 percent, correct?
A. Correct.
Q. And you've seen that in the literature as well, correct?
A. Yes.
Q. Return to the OR for urinary retention, retropubic rate was 1.2 percent and pubovaginal was 3 percent, correct?
A. Yes.

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Q. And that's consistent with what you read in the literature as well, correct?
A. It's a little lower for retropubic than I -- but, okay.
Oh, I see, I'm sorry, I didn't break it down. It's in the same range. It's okay.
Q. So for all those voiding variables, the TVT doesn't have higher complication rates than the pubovaginal sling, correct?
A. For the voiding?
Q. Variables we just went through, TVT does not have a higher rate of complication than the pubovaginal sling, correct?
A. Correct.
Q. Groin pain, pubovaginal is .3 percent, retropubic, 1.5 percent, correct?
A. Retropubic was higher, yes.
Q. Now, when we looked at your AUA guidelines, the table you guys